1 2	UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF FLORIDA WEST PALM BEACH DIVISION
3	CASE NO. 20-md-02924-ROSENBERG
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5	IN RE: ZANTAC (RANITIDINE) . PRODUCTS LIABILITY . West Palm Beach, FL LITIGATION July 9, 2020
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9	VIDEO CONFERENCING CASE MANAGEMENT CONFERENCE
10	BEFORE THE HONORABLE ROBIN L. ROSENBERG
11	UNITED STATES DISTRICT JUDGE
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13	Official Court Reporter: Pauline A. Stipes
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THE COURT: Okay, good morning, everyone.

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I know most of you are here, there are a few who are remaining to join us this morning, but in the interest of time and not wanting to keep others waiting, we are going to proceed, and I thank our cohosts for working so diligently for the past half hour to admit what is now approximately 184 attendees to the status conference. This is our second formal status conference in the Zantac MDL, and I welcome all of you.

I have a few opening remarks that I would like to make and have written those down, so I apologize if you see my eyes looking over to the right because I like to be true to the thoughts that I have considered carefully that I wanted to convey here today, and then I look forward to turning over the agenda and the comments to the presenters who have carefully also thought through the issues they felt on behalf of all of the parties were important to address here at the status conference today.

So, with that, I want to first say that I hope that everyone is well, everyone is healthy and managing the pandemic as well as we are all able to do so.

I am grateful that we do have this opportunity to get together by Zoom, even though it is not in person. One day soon, hopefully, many of you will be able to come to the courthouse in Florida and we will be able to meet in person, but as I have always said, it is most important that we remain

safe, and while we can continue to conduct our work through the benefits of technology, that is what my intention is until there comes a day when I feel and you feel that it is safe to travel and to come visit us in Florida in person.

I am grateful that so many people can and are participating today through Zoom. I am not sure that if we had this in person we would have 185 people. So, yet, one of the advantages that I always point out when we get together through Zoom is that it does enable more people to participate than might otherwise be possible, and I think that that is a good thing, particularly in a case like this.

I know that most of you will not be speaking here today, not all 185 of you, or we would be here for awhile, and I know that I cannot see most of you, but I want you to know that I appreciate your attendance, your participation in this litigation, and your interest in keeping apprised of the litigation.

I want to thank everyone who has helped make this conference possible. In these times when we rely so heavily on technology we would not be able to proceed without the support that we are all so fortunate to have from our IT teams, from our staffs and those who work closely with us each day to help us continue our work, our important work during this pandemic. So, we should all take the time each day to thank those who support us on a regular basis.

I also recognize that our means of communication have taken on new forms with technology platforms such as Zoom, and as I have said before, I have observed and come to greatly appreciate the many advantages that come with counsel meeting in person, so to speak, by Zoom or other platforms as opposed to sending text messages or emails or even speaking by phone.

This case has highlighted for me what can so successfully be accomplished through effective communication, collaboration, and coordination and the value of doing so in person, albeit virtually. I believe there is something about seeing one another when communicating that holds us all accountable and lends itself to greater professionalism and respect for one another.

I know that day in and day out many of you are on Zoom calls with your own teams and with opposing teams working together to keep this litigation moving forward in a reasonable, efficient, fair, and manageable way.

I have heard reference made to, quote, unquote,
"Zantac time" as synonymous with the long hours you have been
expending in this case and I want to thank you for all of your
diligent work. It most certainly has not gone unnoticed by
this Court.

I know it has been hard for everyone to juggle work and personal matters during this pandemic, and that you have all had to make great sacrifices to devote the kind of time

that you have to this case and I thank you for that.

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Especially, I want to recognize the coleads for the Plaintiffs and for the Defendants and each of the members of the leadership teams and liaison counsel for leading this large and complex litigation.

I want to thank Special Master Dodge for her tireless commitment to each of you and to the case. And I want to thank Judge Reinhart and my staff and our IT staff, including Ricardo, James, and although no longer with us, Juan, for doing everything they can to help me manage this case so that all parties feel they are being treated fairly and that they have confidence in litigating this case in this Court.

Now, since we last convened our status conferences in mid May, we had two days, if you recall, we had a general status conference and it was followed by a discovery conference coming on the heels of the previous week when we had two days of interviews for Plaintiffs' leadership counsel.

Since that time we have had many new parties, so welcome, welcome to the party, primarily Defendants who have entered the case, and thus one purpose for today's status conference, among others, is to allow the new parties to become more informed about the case. I know you probably have spent a lot of time attempting to get up to speed, and you may feel you are, and I have no doubt that you likely are, but that being said, there is a lot that has been happening and we thought it

prudent to make sure that everybody was on the same page, everybody understood where we were, where we are, and where we have come to in a relatively short period of time and what our vision is about this case and how it will move forward.

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I use the word "vision" and I say "our vision" because I believe that it is a vision that is shared by the Court as well as by leadership for Plaintiff and Defendants, and it is why those particular individuals were selected as leaders and liaisons in this case and why I look to them regularly and try to afford as much deference as possible where appropriate to manage and to lead the case.

Now, there has been much activity in the case since mid May when we last met. There have been approximately 12, or maybe as of this morning, there was a new order entered this morning, 13 pretrial orders. Many of these orders are complex, and they are very involved orders, including orders relating to electronic discovery, a case management schedule, discovery dispute process, master pleadings processes, and orders concerning matters such as confidentiality, preservation, and privileged information, just to name a few.

I would encourage everyone to become familiar with the Court's website, it's on the Southern District of Florida website. I won't get into the details of exactly how to get to where the MDL portion of it is, but you can readily ask anyone who has been in the case for awhile. I refer to it regularly.

To manage the docket is difficult, it's cumbersome, there are a lot of filings, so if you want to get right to the point in terms of knowing what the orders are, I believe we are at pretrial order 33 now, just go to the website and they are chronologically listed. And on the that you will also find any time there is a hearing or case management conference scheduled, that is also a useful place to learn that information.

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I am pleased to say that each one of these orders, each one, was the result of negotiations and collaboration between the parties to arrive at a process that will bring the greatest benefit to the litigation overall.

I recognize that with every negotiation not every party will get everything at once, but collectively the end product has always struck the Court as fair, as balanced, and reasonable.

We have not had one dispute between the parties that has required the Court to intervene formally since the inception of the case in early February, and this speaks, in my opinion, to the success the parties themselves have had in resolving matters before they needed Court intervention.

While I recognize that there will be times when the parties will not able to resolve all of their differences among themselves and come to the Court for resolution, I believe that it is far more effective to have the parties first exhaust

their efforts to work together and with the assistance of Special Master Dodge. This allows you, the parties, to chart your course for your litigation and allows the Court to stay focused on its job in assisting you in moving the case to the next procedural stage or stages in the process and to make the necessary rulings on the significant motions that will be filled as outlined in the case management schedule.

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While I understand that some Defendants, maybe some of the newer ones, may feel frustrated that they are in this litigation because they do not think that they belong in it, let me assure you that there are processes in place in this litigation to provide for careful vetting and winnowing of parties and claims.

We very deliberately included on the agenda an update on the registry process so that those of you who have been in the case for some while can be reminded of this process and, importantly, for the new parties you can hear exactly what that process is, how it works, what its benefits are, and why the Court believes that it is an immensely valuable tool that all parties should strongly consider taking advantage of.

Through the registry process, the parties will have the benefit of becoming educated in a cost effective and efficient manner as to the types of information that would otherwise take a very long period of time to obtain in a case of this size and at great cost to the parties. The leadership

is committed to using the registry to winnow claims and parties so that in the end, if you do not belong in this case, there is a readily identifiable way to recognize that and thus implement measures to address that. We will talk more about that today.

I know that counsel presenting on the registry process will speak more specifically to this, but I felt it important for me to convey my support of this process, and that as you come to understand it, and with some patience, you, too, will see the benefit of the process and why it is such a useful tool to address many concerns that parties may have at this juncture in the litigation.

As we are working through the early vetting processes in place in this case through the registry, and consistent with the Court's emphasis on matters being resolved where possible amongst the parties, and in order not to overwhelm the Court resources on widespread motion practice, the Court encourages everyone to familiarize yourselves with the process that the Court has put in place for motion practice. I felt it important to highlight this particular pretrial order because it may be on people's minds as to how motion practice works in this case.

This case is different than non-MDLs, and may even be different than other MDLs because of the unique complexities, the nature of the claims, the number of parties involved, and so one of the pretrial orders that again had also been

negotiated by the parties and adopted by the Court is pretrial order number 24, and specifically paragraph ten, and you will find that it fits within the Court's and the leaderships' vision of how this case, again, should be litigated and managed and speaks specifically to motion practice.

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You will read it, if you haven't already, but in sum, that paragraph speaks to how motion practice would be handled in this case, other than as to those motions that have been outlined in PTO 30, which is the pretrial order that addresses the case management schedule and there are certain motions that are specifically identified in that order, specifically Motions to Dismiss, Daubert Motions, Motions for Class Certification for example.

Other than those motions, PTO 24, paragraph ten, speaks to how motion practice will be handled in this case at this time.

The Court is open to revisiting processes if it finds that some aren't working and it will be an evolving process. I can assure you that the Court is sensitive to hearing concerns and making necessary adjustments where needed.

In this PTO motions are not to be filed before conferring with the coleads for their consent and then with the Special Master. If the coleads do not consent to the filing of the motion, leave of the Court must be sought to file the motion if a party still wants to file the motion after

conferring with the coleads and the Special Master.

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So, to be clear, nobody is precluded from having your day in court and having your individual issue heard before the Court if, after conferring with colead and either not receiving their consent or receiving their consent — then the motion would be filed with their consent. If there is not consent because of the better judgment, or different judgment, I should say, held by colead and you are not able to work it out through Special Master Dodge, you can seek leave of the Court to file the motion and that will be an opportunity for the Court to hear why you feel — despite those earlier steps, you still feel that the motion should be heard.

So, everybody has their day in court, I want everyone to know that, that is important, due process, adherence to the rules, but it doesn't mean that the Court can't and has not implemented certain processes that it deems, in conjunction with leadership, to be best suited to manage this case, again, in an effective, efficient manner. And you will hear those words used a lot as I describe my vision for managing the case.

There is also the issue, I recognize, that some cases have recently been transferred to this MDL or will continue to be transferred to this MDL, and if any of those cases being transferred have motions that were filed in the transferor court, those parties must nevertheless follow the process for motion practice set forth in PTO 24. I thought it worth

addressing that as well.

First, your motions will be part of your individual case and not part of a larger MDL, so there really wouldn't be a pending motion in the consolidated MDL, it would be part of your individual case that had been transferred over, and thus the motion would not be ripe for the Court's disposition in the MDL.

Second, there may be reasons for the motions to be rebriefed given that they are now in a new court. I don't know that, but that is a possibility given you are now in a new court for those cases that have been transferred over with motions that may or may not have already been briefed in part or in full.

Lastly, but as importantly, the Court wants all parties to adhere to the motion practice processes that are set forth in PTO 24 because it believes it is the right process for managing this MDL. You can only imagine that if every party wanted every issue to be heard through motion each and every time that an issue arose that the Court would be overwhelmed and would not have the necessary resources to manage the breadth of this case.

So, with that, let me turn the agenda over to the team that will present on the topic of the registry. We refer to it as tolling and/or vetting. If I can remind counsel who will be coming on the screen now, you can put your videos on and unmute

yourselves, that before anyone speaks if you could always please state your name so that it is abundantly clear that your comments are attributed to you for purposes of our record. We have, as I said before and bragged about her, Ms. Stipes, the best court reporter there is, and she is a perfectionist, so she wants to make sure she gets your names and that she hears you. So, each time you speak, don't be shy, just state your name again.

I have asked Mr. Pulaski, Ms. Finken, and Mr. Petrosinelli to start with the basics, knowing that we have new Defendants coming in and upcoming deadlines for Plaintiffs, so that we can get everyone up to speed because this is a unique process designed to deal with some of the complexities of this case.

So, if I understand from the agenda, but feel free to correct me if I am wrong, Mr. Pulaski, are you going to begin with an overview of the presentation on the registry?

MR. PULASKI: I am, and good morning, your Honor.

Nice to be here by Zoom, I appreciate your accommodating everybody and your willingness to get this started even though we can't make it in person.

Let me start, and I don't want to beat a dead horse because I know we have gone over this process several times, but as you mentioned, there are a number of new parties involved here that have not been involved to date, and so I

want to just briefly go over the Census Plus and registry program for their benefit.

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I know that I have had several conversations with brand manufacturers, with generic manufacturers, with retail manufacturers along the way, so this will be repetitive for many of them, but I will try to make this first point very brief.

Overall, the Defendants' and the Plaintiffs' lead counsel spent a very long time, along with Special Master Dodge, negotiating the registry program at the guidance of your Honor and what we came up with was a plan that we think allows for efficiencies both in time and in money and a process that will allow this litigation to move forward in a manner that gives transparency and clarity to everyone as it relates to everything having to do with the census.

So, for instance, part of the census is there is a Census Plus form that will need to be filled out by everybody that is part of the registry process. This Census Plus form is very detailed, has a lot of data in it on behalf of all of the claimants. That includes the types of cancers they may have been diagnosed with, the retailers where they may have purchased the products from, the time periods in which they purchased and used the products.

The Census Plus form, again, while it was negotiated by Defense and Plaintiffs, will allow data that I think -- and

Mr. Petrosinelli will touch on this later -- will provide a lot of guidance to the Defense so that the Defense will know how many claims potentially may be targeted against their client, the lawyers will be informed of that and, really, just give guidance to this along the way for the entire litigation.

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There is a tolling aspect to this litigation and a census registry that is vital for the efficiency aspect of this.

So far we know of over 50,000 cases where clients have retained attorneys. In the initial census that we had before leadership was appointed there were 42,000 cases that were filed in the initial census. I know that of those 50,000 cases, I have personally spoken with a very large number of Plaintiffs' firms, they are working very hard and fast to get their Census Plus forms filled out and entered timely.

There is an August 21 -- I am sorry, there is a July 21st deadline for the Census Plus forms for anyone that has filed a case. There is an August 17th deadline for anyone who retained an attorney as of June 1st. So, by August 17th, I think you will see tens of thousands of claims in the Census Plus registry that will provide data not only for the Plaintiffs, but for the Defendants as well.

In addition to that, just obtaining the data, it kind of makes the MDL the focal point of this litigation, and in addition to the CPF forms that are filled out, there is also a

method now set up by the Defense and the Plaintiffs for a very quick recovery of proof of use and proof of injury records that I have discussed in detail with brand manufacturers, with generic manufacturers, and with retailers, and now also with the distributors.

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And so, the overall process itself just for the registry is, like I said, very efficient I think. Special Master Dodge, the entire leadership on the Defense side and on the Plaintiffs' side worked very hard to create this method that will bring efficiencies to the litigation.

We got here because of the fact that in this particular litigation we have not only four brand manufacturers, but we have over 50 retailers to a hundred retailers that could be involved. We have over 30 to 40 generic manufacturers that may be involved. We have distributors that could be involved, repackers that could be involved. So, the dynamic of the litigation really calls for this efficiency because without it, it would become unwieldy.

Why we think everyone should be saying yes to this, agreeing to the terms of PTO 15, agreeing to tolling, agreeing to the registry process, are for these efficiencies, and not only that, for what we think will be a very important aspect of the vetting process that really gives the Defendants a seat at the table for vetting unlike we have seen probably in any other litigation.

Let me kind of explain what I mean when I say the Defendants will have a seat at the table for vetting.

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In addition to all of the benefits that the CPF gives us with respect to being able to select sample pool cases because of the data that's in there, or select potential bellwether cases, we will have certain information if we are given it in advance by generic manufacturers, by retailers, that will allow us to easily identify which manufacturers are proper parties in an individual case, and more importantly, be able to determine which manufacturers are not proper parties in a particular case.

What I mean by this is that if we are able to build a timeline and if we are able to create a blueprint for the Plaintiffs' bar, and for this entire litigation, by obtaining data that tells us manufacturer A produced and marketed and sold this product from 2000 to 2005, and that they produced and manufactured this product in a tablet form, and it was a 300-milligram tablet, and it was only sold in the western hemisphere, the western part of the United States, and not in the eastern part of the United States, we will be able to build for every single generic a timeline, every single brand manufacturer a timeline that will allow us to then send a message out to the Plaintiffs' bar in a very concise and detailed format that will show if your client, John Doe, only took Zantac or Ranitidine within the years of 2000 to 2011,

then we know for sure that there are, for instance, 26 generic manufacturers that could not have been — that could not be a proper party to the case because they didn't market or sell their product during that time period.

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Without this information it is going to be almost impossible for us on the Plaintiffs' side to determine with particularity which Defendants should be made proper parties in every single case.

Our goal on our side is to be as efficient as we possibly can as to only name those parties that are proper in a particular case, and again, more importantly to exclude parties that should not be part of a particular case.

By agreeing to PTO 15, by agreeing to tolling and providing us this minimal amount of information, it will allow the registry to function as it was intended. It will save everybody, both on the Plaintiffs' side and Defense side and for the Court, time and money.

I know Mr. Petrosinelli will talk on his portion about the vetting process, but for our portion, we don't view this registry just as a tool to -- you know, as you would see in a normal litigation, have a fact sheet to use for choosing a sample pool and ultimately ending up with your selected bellwether cases, but we are using it because of the complexity of this litigation as a vetting tool that will truly benefit all Defendants and Plaintiffs alike.

So, it is very important that we get the brand manufacturers, the generics, and the retailers and distributors to buy into this registry process so that it can function as it was intended.

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Briefly I will talk about the tolling aspect of this and some problems that we currently face.

And again, Mr. Petrosinelli will also be talking to this as it relates to Defendants, but we have tolling as it stands with the four brand manufacturers, a handful of the retailers, and a handful of the generic manufacturers.

What we don't have is tolling against all of the generic manufacturers and all of the retailers.

So, for instance, in certain cases it makes it impossible to really receive the benefit of any tolling because if we don't have tolling amongst all parties in a case where we may have a claim against a brand manufacturer, a generic manufacturer, one or two different retailers, and we only have tolling as to one party, the case still needs to be filed because we have to protect our clients' claims and we need to file the cases timely before the statute passes.

In addition, we need the statute so that we don't have to file claims and we could properly vet these claims based on the information that we hope we will be given by the generics and by the retailers and by the brand manufacturers so that we can put the timeline together and properly vet the cases.

I will leave the rest of the tolling issues as it relates to the brand manufacturers, the retailers, and the generics, as well as the distributors for part of Mr. Petrosinelli's conversation.

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What occurs if we do not get the tolling and the buy in for PTO 15 that we have -- again, both Plaintiffs and Defense worked so hard for, is that we will be unable to determine, for instance, which generic manufacturers may be a proper party, and we will have to be over inclusive rather than much more narrowed and targeted.

For those Defendants who are not in agreement, there will be a very large number of lawsuits that will be filed both in State and Federal Court over the next several years, not only against those Defendants who are not in agreement, but against those Defendants who have also agreed to tolling, but for the reasons I stated earlier, it will be impossible for us to just file a lawsuit against one Defendant, for instance, that didn't agree to tolling. We will need to name all of the Defendants who have also agreed to tolling in PTO 15.

We are currently working on what we think is a very generous plan for the generics and for the retailers for limited discovery for those that have agreed to PTO 15 and tolling, and again, this is part of a give and take that we have had over now three or four months of negotiations.

We do not have agreements with the generics at this

time that I know of, unless it occurred this morning. We are working towards that. I know the negotiations are ongoing. We have ongoing negotiations with the retailers that we will talk about later, as well as talking about the plans with the generics.

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But suffice to say, without these agreements we will have to begin full and complete discovery which, again, for efficiency's sake, while we vet out the types of cancers that may or may not be involved in this litigation, while we vet out issues as they relate to which Defendants are proper parties based on the timeline and blueprint that we will be able to build out with the information that is given to us. And, again, like I said, not in any other litigation I don't think have we had the opportunity for the Defense to play such a large role in the vetting process as we have here today.

So, with that being said, I know there are a couple of different sections of this presentation, and I know Mr.

Petrosinelli has a couple of items he wants to discuss, so for now I will turn the table over to Joe and let him start his portion of the presentation.

THE COURT: Okay. Let me just ask before Mr. Petrosinelli jumps in, did Ms. Finken have any points that you wanted to add to Mr. Pulaski?

MS. FINKEN: No, your Honor, not at this time.

THE COURT: Great. All right. Let me know if you do

after Mr. Petrosinelli addresses the Court.

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MR. PETROSINELLI: Thank you, your Honor, it's Joe Petrosinelli, I am a lawyer for Pfizer, but also one of the Defense coleads. It is good to see you, good to see Mr. Pulaski and Ms. Finken, too, but I see them all the time so that is a little bit less exciting to me.

I wanted to -- I won't repeat what Mr. Pulaski said.

I will just give you Defense perspective on this, which is that

I think what we are facing at the start of this MDL, as Mr.

Pulaski alluded to, is the filing of thousands of claims given

the size of the MDL, the length of time the product had been on

the market, and indeed, in my experience that is what one would

normally see when an MDL gets created, is an influx of a large

number of filings in a case like this with a product like this.

And I think that would have forced Plaintiffs, as Mr. Pulaski referred to, to file lawsuits where they might not know who actually manufactured or sold the product that they took, or they might not know whether there is sufficient scientific proof with respect to the injury they are alleging.

Creating this registry sort of allowed that vetting that Mr. Pulaski referred to -- a place for that vetting to occur outside the context of actual filed litigation, and I think that is very beneficial to all parties.

I think for the Defendants, as Mr. Pulaski referred to -- and I will talk about in a second how we see the

process moving from here, but it allows for a narrowing of claims that might actually be asserted against anyone's individual client. Also, there is a provision in PTO 15, as the Court knows, that requires if you submit into the registry, that if you file your case, you will file it in the MDL. I think it benefits all parties to have one main centralized proceeding where common discovery can occur and common issues can be decided.

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So, that is a big benefit, I think, certainly for the Defendants and I think for the Plaintiffs as well.

Now, a tradeoff for that was to grant tolling of the Statute of Limitations to these particular claimants' claims, and it is true that many Defendant — maybe most Defendant companies don't favor tolling, but I think in this instance the tradeoff for us and the benefits that we think the registry can provide were worth that give during the negotiations, and as your Honor alluded to at the outset, this was very much a product of collaboration and negotiation where we ended up. I think it is a very unique procedural case management device in MDL litigation, and I think it fits this MDL.

Tolling only makes sense, though, if in fact the vetting process that Mr. Pulaski talks about happens, and that gets me to what are the next steps that we see, and they are the following:

I think, as Mr. Pulaski referred to, between July 21st

and August 17th, the initial tranche of Census Plus forms will come in, and when they come in we will have our vendor — the joint vendor will need, I'm sure, a little bit of time to look at the data, run reports and so on, but it is at that stage that PTO 15, as the Court knows, always contemplated — expressly contemplates that we would come to the Court with additional orders that are needed to implement the census process.

And the next sort of order that we anticipate that we would be working on in this time period when the forms are coming in, hopefully for presentation to the Court at or before the next status conference, is an order that would really address three things.

One is how to deal with deficiencies in submitted forms. When I say deficiencies, I mean where someone, for example, hasn't filled out an important data point in the forms. Just as an example, the form asks: Did you take prescription or over-the-counter Ranitidine? If that is left blank, that is not helpful, so a process for figuring out how those deficiencies and when and under what schedule they get corrected. So, that would be one thing.

The second thing would be perhaps as or maybe even more important to the Defendants, what I call product ID, but basically, given what the claimant has said, the product they took, when they took it, maybe where they bought it, to figure

out which Defendants that the claimant may have named in his or her form as contemplated Defendants actually could even conceivably be the correct Defendants in the case. As Mr. Pulaski says, and it would be my experience, that claimants might be over inclusive in the types of people they include perhaps because they don't know, but that we would be able to then narrow the universe and each of the Defendants and their clients could understand how many cases — potential cases because these aren't filed cases yet, but how many even potential claims could we be facing in the litigation.

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That is important if you are a company to know for all sorts of reasons that are obvious, not the least of which is to figure out how much resources you are going to dedicate to the litigation, and so on.

Third would be, even if a claimant has filled out his or her form correctly, that is to say there are no deficiencies, and they have and identified dates and what product they allegedly took, to get the proof of use and proof of injury, that is kind of the hallmark of an initial census process and to figure out — for example, if a claimants says, I took prescription brand Zantac in 2015, that is what the form says, but if we look at the prescription record and it says they actually took a generic version in 2012, that is a big difference because it sort of eliminates a whole host of potential Defendants and it includes others, and so that proof

of use and proof of injury provision will be an important part of the PTO that we give to the Court.

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Frankly, and I think the Court intends this as well, if someone can't provide basic proof that they have the injury they are alleging, or that they took the product, that those claims would be exited from the registry after some fair amount of time to get that information.

And so, those are the things we are going to be working on over the next 30, 45 days to be able to present to the Court that that order, or series of orders that was contemplated in PTO 15, so that -- and I would say, finally, there would then be a process for amendment of the claim forms.

In other words, if the records show -- or if the information that the Defendants provide about when and how and where they manufactured show that the form as filled out by the claimant is not correct, it couldn't be Defendant X who manufactured the product that was taken and so that Defendant can't possibly be correctly included on the list of anticipated Defendants, that the forms would be -- I will use a colloquial term -- cleaned up to identify at the end of the day so we have an identification and we have a database or a repository of what the claims really could and should be as the litigation moves forward.

So, I think that, too -- Ms. Finken I know has been working on this, but that, too, in the order would sort of

specify what information is needed from Defendants to get there. In other words, to figure out who manufactured what, where, how, when requires the Defendants to provide that information to the Plaintiffs. I think the Defendants will be quite eager to provide that information because it provides the basis for showing that their client or clients don't belong in X percentage of the claims that have been filed.

So, when your Honor talks about a vision, like that is our vision for the next -- I don't know exactly when the next conference will be, but in the next 45, 60 days, as the forms come in, we work on that order, present it to the Court, and then we can get going on the vetting process that I think we all want to do. It will help the Court manage litigation going forward.

So, from the Defendants' perspective, that is what we see as the benefits of the registry, as the benefits of the tolling that we have agreed to, we, I mean the brand manufacturers and many of the other parties that have started to enter the litigation have agreed to so far. Those things are what we see as the next steps as we move forward and the Court attempts to officially manage a litigation of this size.

And all of this -- I guess my final thought would be to Mr. Pulaski's point about Defendants having a seat at the table, all of this would be done in the context, and done early in the context of a registry as opposed to having to deal with

it, individual Motions to Dismiss filed complaints which, as the Court noted at the outset, the Court has indicated that presumptively individual motions are not going to be dealt with early in the litigation, and I think that is a common provision in MDLs.

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So, instead of having to deal with this and file cases with individual motions in those cases perhaps later down the road, we get to deal with this up front with a hand in dealing with it in the context of the registry which I think provides significant benefits to the Court and certainly to the Defendants.

So, thank you, your Honor. I would be happy to take any questions, but otherwise I pass it to Ms. Finken.

THE COURT: Thank you, Mr. Petrosinelli.

Did you want to add anything, Ms. Finken?

MS. FINKEN: Yes, your Honor. It's Tracy Finken from Anapol Weiss on behalf of the PSC.

There are two parts of this process in terms of the product identification and the vetting process that would be helpful from our perspective with the registry process to really narrow the focus on who should be involved in each individual case.

One of the issues is getting the information that we need from the retailer Defendants in terms of loyalty rewards programs and prescription records that they have readily

accessible and that is something that we are in the process of working through with the retailer Defendants and we'll discuss in more detail later on during the conference when we get to the point that we talk about discovery with those Defendants.

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The other thing that would be really helpful for us in terms of narrowing the focus that goes along with what Mr. Petrosinelli was saying and what Mr. Pulaski was saying, is that if we had in some uniform manner from each Defendant certain information, and the information that would be helpful to us is really identifying the years that they manufactured, distributed, sold the product, whether it was Zantac or Ranitidine, the markets or regions where they were selling the product during those years, the specific formulations that they marketed, sold, manufactured, the prescription versus generic formulations, as well as the retailers that they were contracting with to sell their products, and market share as well as some of the NDC codes -- or all of the NDC codes that were associated with the products that they manufactured, sold, and marketed would help us in the process of really narrowing the focus and narrowing the issues for each individual claimant.

To be candid, some of the Defendants have provided this information informally to us through the meet and confer process, but it would be really helpful from our perspective if we had a uniform process for each Defendant to provide this set

of information to us so that we can really plug this into the registry process and narrow which claimants belong in which buckets of information there.

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So, something along those lines from each Defendant would be very, very helpful for us to really properly vet these cases within the registry.

THE COURT: Do you see that as something that lends itself to an order? And if so, would this be a type of order that Mr. Petrosinelli was discussing as you working on over the next 30 to 45, or 45 to 60 days, you gave both timeframes, in terms of the series of orders contemplated in PTO 15? Is that an example of one?

MS. FINKEN: Your Honor, it is not an order that we discussed, so to speak, with Mr. Petrosinelli, but an order, I believe, would be helpful in that it would require the information to be provided to us in a uniform way so that we are getting the exact information from each Defendant and it would also help us to narrow the focus.

There are certain Defendants that have indicated, while they have held an ANDA for a particular product, they never actually manufactured or sold it. It would allow us to gather this information in a uniform manner so we could properly identify appropriate Defendants in the litigation versus those that maybe are inappropriately named in the Master Complaint due to misinformation that we are gathering from just

publicly available regulatory filings.

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So, if an order would be issued having the Defendants provide that information uniformly, I think it would be very helpful for our purposes for vetting and identifying the proper and appropriate Defendants in the case.

MR. PULASKI: Your Honor, if I may, when you mentioned that this was an order that would be one that we would discuss over the next 30 or 45 days, this is really of particular importance and is time sensitive at this point because claims are being filed because we don't have the tolling agreements in place yet, and we are having to file claims.

And again, as I discussed earlier, I have had several conversations, along with Special Master Dodge, with a number of the generic manufacturers, just as an example, who have called to state that perhaps their client shouldn't be named in a particular case because of the time frame, or because of the year, or because they never actually used their ANDA.

And in order for us to stop the bleeding at this point and really start working on that timeline and working on that blueprint so that we really can start our vetting process now, I would suggest that if there were going to be an order in that regard that it be — that your Honor would enter it much sooner than 30 to 45 days.

Maybe perhaps we do that almost immediately so that we can, you know, really -- for instance, if -- again, as an

example, I have had multiple conversations over the last few weeks of Defendants who have said, hey, I can't be involved because I only sold this product during this timeframe, and I can tell you, your Honor, that I have been communicating with LMI, I have been communicating with Cerner to pull data so that for my own benefit I understand exactly how many potential claimants are out there that took a product, say, between the years 2005 and 2011, that took a particular product, and I look, oh, it is 2,346.

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And I can have the conversation with that manufacturer and say, I understand you sold during this time period and you don't think you should be involved and, in fact, A, you are right, I only have one claimant out of 42,000 that ever took your product in this time period, or in fact I think you may be misguided a little bit and have some misinformation because I show that 2,300 of our clients took a product that could have been yours during this timeframe because you sold product that fit all of these different criteria that we have information from the initial census.

So, I cannot do that with most of the people I am speaking with because I don't have the information that Ms. Finken was talking about as it relates to did you sell a generic or a brand, or over the counter or prescription? When did you start selling? When did you stop selling? What were your limitations on distribution, was it only in certain

regions of the country or was it the entire country? Did you only sell single dose versus regular over the counter? Did you sell capsules, or tablets, or whatever?

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And so, to us, and really to help -- and I have been pounding my head against the wall to explain that I really -- on this particular issue, I am not against the Defense, I am with the Defense. We want to make sure that we vet the cases, we want to make sure that we name the proper parties.

I have had the conversation with Mr. Petrosinelli, I have had the conversation with Special Master Dodge, and with the lawyers for the Defendants that we have been talking to, and it would be immensely helpful not only for the registry process, but for the litigation and for the clients of all the lawyers I have been speaking with if we have that information almost immediately.

THE COURT: Mr. Petrosinelli, do you want to respond?

MR. PETROSINELLI: Yes, your Honor. Joe Petrosinelli
here again.

I think it is fair that -- I think we planned on -pending hearing from you, we planned on talking about this in
the more near term, again, as long as it is part of a process
of how we are going to get to the vetting. I think, as
Ms. Finken said, many Defendants have already provided this
information informally. I think other Defendants would want to
provide it because, as Mr. Pulaski says, it is a way to

actually not get named in cases.

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And so, yes, I do think that our plan was to -pending hearing from you at the conference, our plan was to
talk expeditiously about this to see what is the best way to
get -- and streamlined way to get this information to the
Plaintiffs so that we can implement PTO 15 and the vetting that
is contemplated by it.

THE COURT: Okay, terrific. Well, I am very supportive of that and so I would stand behind the remarks made.

I know we are going to talk about other matters relating to production, but on this one point, it sounds like, at least as among the leaders on the presentation right now, that you are all in agreement, and it seems very logical and reasonable to the Court as well.

Perhaps at this stage, if product ID is front and center an order can be addressed to provide for the efficient and timely and orderly turning over of that and then other orders if needed provide for other information, there is nothing to say that everything needs to be held up because there can't be agreement on all points, but if there is agreement on a very important point, in the spirit of vetting and winnowing and clarifying, that seems to be a very obvious focal point for the parties to continue and to present the Court with anything the Court can do by way of an order that

would be helpful to ensure that that process is fair and reflects a balanced approach.

So, thank you for sharing that.

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I did want to just kind of reiterate while you are still on the screen, and then feel free to add anything further, what I said in my earlier remarks, that I believe the registry is a very good system and I believe it even more now after hearing from each of you eloquently describe its advantages to both sides which is unique.

It was developed through a very extensive and collaborative process between excellent counsel on both sides to address the very unique challenges presented by this MDL. It is an innovative structure, it's designed to allow for a better process for vetting, and for years Defendants have asked for early vetting, but this system is unique in that it allows a Defendant to participate in what the vetting would look like before the cases are even filed and the existing PTOs have given the Defendants a seat at the table.

I just want to remind everyone else who is not on the screen right now, particularly some of the newcomers, to remember that it will take at least some time and that patience is needed, but I also want to remind everyone that my support for the registry should not overshadow my adherence to each party's due process rights, and if a Defendant does not want to agree to the registry, of course that is their choice.

I want to make sure it is clear that if parties don't agree to the registry and complaints are filed against you that would otherwise remain as claims in the registry, as I said earlier, it is not the Court's intention to address alleged deficiencies with short form complaints through motion practice, as I have already set forth in PTO 24 and my explanation of that order here today.

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Alternatively, you have heard the presenters, and Mr. Petrosinelli in particular, talking about the process for dealing with deficiencies in the registry, and it's built into PTO 15, and I think you indicated that was one of the orders that you would be working on.

So, if there were deficiencies, would there be allowance for an amendment to the claim form, and it just seems to be a very robust system that doesn't clog the Court system, but is kind of going on in tandem, on a parallel track, the Defendants aren't being named in multiple cases, in court cases, but are sort of sorting these issues out through the registry.

There were a couple more points I just wanted to make sure I made about that. If a Defendant does not agree to the registry, as Mr. Pulaski indicated, the Plaintiffs will perhaps feel they are in a position where they must file their complaint shortly, and we may see an even larger number of cases and therefore more cumbersome litigation which will call

upon the Court's resources in an even greater way to manage this MDL, as well as potential State Court litigation.

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Now, I do understand that the Special Master has already granted short extensions of time to a subset of parties who she believed would benefit from being able to hear the remarks today before making their election. I hope these remarks have been helpful to those parties and the representatives here today.

I have granted her the authority, you should know, to continue to make these accommodations, but it is my considered hope that after today you will have enough information to understand the consequences of either path and will be able to make your election in the next few days so that we can move into the next phase of this process.

I also understand conversely that there may be some Defendants that after today know they want to participate in the court registry system rather than require the filing of additional cases, but they have not yet filed a notice of appearance in the case. I understand the reasons for that and I encourage you also to reach out to Special Master Dodge who will be able to inform you and to inform Plaintiffs of the entity's election without revealing counsel's identity if so requested, so there are no issues there, and that can be addressed in that fashion.

I moreover want to assure you that if counsel want to

work with Plaintiffs and/or the Special Master before filing your notice of appearance, or if you want to assist liaison counsel in the preparation of her spreadsheet tracking service dates this will not waive your arguments about service in this Court's eyes. I wanted to give you all that assurance here today, and that you can assist Ms. O'Connor, Defense liaison, and the Special Master in that task without any waiver of your rights. I hope that that is helpful.

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Let me just see if I had any followup questions while counsel are still on the screen because you may have preempted them in your remarks.

So, if I could just by way of example, Mr. Pulaski, and again for the benefit of the Court and those who are on the conference and would be interested in hearing this, we know that PTO 24 does not contemplate individual specific motion practice short of going through the process that I have outlined, and so I expect that you are — and it seems like from your comments that you are working with the Special Master starting to get your arms around the issues to resolve them informally and good faith. I understand that orders are being worked on and immediately and over the next 30, 45 days.

Just to give us an example, Mr. Pulaski, where are we exactly on starting to go through a Defendant that says it never manufactured. You must have an example where a Defendant has come to you and said, I have never manufactured.

How are you handling that today, and what assurances can you give those Defendants as to the timeliness of addressing those kinds of concerns?

MR. PULASKI: Yes, your Honor, I am happy to answer that.

Again, through numerous conversations we have had, there are — and I talk about generic manufacturers as opposed to retail Defendants because there is a difference. I have had lengthy conversations with Ms. Johnston about this, that it is a lot easier to determine who your retail Defendant is because you know you walked into a CVS or you walked into a Walgreen's. You may not remember every single place that you walked into right off the bat, but it is a much easier determination of who the proper Defendant would be.

In this particular instance with generic manufacturers, and why I keep bringing them up, is that most people don't know who the generic manufacturer is when they purchase a product, so we are relying on the information from the clients of the attorneys that I have been speaking with to guide us so we can dismiss those that shouldn't be involved.

For instance, if someone tells me that they purchased an ANDA as part of a bucket of goods, but never used it, never manufactured it, never sold it, never marketed it, never did anything, what we have asked for is the information that Ms. Finken related to you in the form of, hey, could you please

get me an affidavit that states this, we purchased the ANDA, we never marketed it, we never sold it, we never used it; or, hey, I only marketed the product from June of 2019 to August of 2019, so this particular client who stopped using it in 2018 couldn't have used my product, and I have asked for the same information, give me an affidavit of when you purchased the product, when you marketed it, when you sold it, where you marketed it.

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We will be happy, if it is a case I filed or a case another lawyer filed, to reach out to that attorney and make sure that you are dismissed out of that case. While I trust Defense lawyers impeccably to tell me the truth, we just need some verification from their clients so that we can make a responsible determination to dismiss them out of the case and we will do it posthaste once we get that information.

I have -- I am consistent with that message to every attorney that I have spoken with so that there is not a different message for one attorney to the next, and that, again, is why, if you were to enter an order requiring that basic information to be provided to us, we wouldn't even need to be having this conversation. It would be over before it started and -- we just wouldn't need to be having this conversation.

For those that have already been filed, to answer your question, my goal is to get that information from them as soon

as they can get it to me, and once they do get it to me, make the determination to dismiss their client from the case within a very reasonable timeframe.

THE COURT: Okay. So, I think that is good for those Defendants who have already approached you and others who may not, but didn't know or fully understand how this works. So, you are available for them to reach out to you regardless of when an order may be forthcoming. With respect to the types of information that Ms. Finken spoke about, you have made it very clear here on the conference. So, if somebody is here on the conference, they have heard the information. You get that information, it shows that they didn't manufacture at the time, or at the place, or in the way that you've alleged, and you would move hastily to dismiss.

I understand perhaps it would not be reasonable to expect you on a daily basis or an hourly basis to be dismissing Defendants, but perhaps you have a very orderly process in mind where you would capture all of the Defendants so as to do it in an orderly way that also would be sensitive to our Clerk's Office in terms of how that would work and getting those dismissed. And you would be keeping those Defendants apprised, so if they didn't feel, for example, you were doing it hastily enough, you would explain, well, actually we are, we have it ready to go, we have a few others, and we are going to do it all together next Friday, that kind of thing.

Is that sort of a sensible way to read --

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MR. PULASKI: That is very accurate, and again, as you stated, they can email me, they can call me, I am happy to get on the phone with them, and I have been, and I will continue to be until we resolve the issues for the cases that are already been filed. Hopefully, if we get this information from all of the Defendants, the minimal information so that we can make the determination, we won't have this conversation again.

THE COURT: So, it sounds like there is a mutual interest. Defendants who don't believe they should be in the case want to get out of the case, and the Plaintiffs don't want Defendants in the case who shouldn't be in the case.

MR. PULASKI: That is about right.

THE COURT: Okay. All right. If there is anything more on the registry, speak now, otherwise I am going to move on to hear from Mr. Yoo on behalf of the generics. I don't know whether Mr. Barnes is going to join him or not.

Did everyone feel as if you said everything that you wanted to say on this topic of the agenda?

MS. FINKEN: Yes, your Honor.

MR. PETROSINELLI: Yes, your Honor.

MR. PULASKI: I did, your Honor.

THE COURT: Okay, thanks so much.

If I could call upon Mr. Thomas Yoo, and I have you on the agenda. I didn't know whether Mr. Barnes was going to join

you or not. It is fine if he does, it is fine if he doesn't.

And I understood the topic to be perhaps short form complaint process, if I understood that correctly.

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MR. YOO: Yes, your Honor, good morning. Good morning, everyone. Mr. Barnes is on, and I think he will let me do the talking until I mess up, so let me get started.

This is, I think, in the same vein as the discussion we just heard regarding the registry, but it is with regard to a different document, and that is the short form complaint.

Plaintiffs have begun to file short form complaints. The big deadline is coming up in a few weeks. We have already started to see some deficiencies in some of the short form complaints. We anticipate we may see more deficiencies.

What we wanted to do today, your Honor, was to identify this issue and simply ask that we begin a discussion with Plaintiff's counsel to try to come with a mutually agreeable procedure by which we can have these deficiencies cured efficiently without the need for formal Court intervention.

The deficiencies we have seen include things like a Plaintiff not providing information about what type of product they used, leaving blank the question of whether they used prescription or over-the-counter product.

Additionally, in the section that is designed for a Plaintiff to write in the names of the Defendants that he or

she has chosen to sue and presumably has a good faith basis for suing, a Plaintiff wrote in something like all Defendants named in the Master Complaint, which obviously is not the purpose and design of the short form complaint.

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So, right now we haven't seen a lot of these deficiencies, but again, the major deadline hasn't come yet, so before we get an influx of these issues and we have many different counsel running around contacting many different Plaintiffs' counsel or bombarding Special Master Dodge with the same issue, we thought it made sense to start a discussion with Plaintiffs and see if we can implement a procedure that will be available for people to utilize as they see these issues.

I raise it on behalf of the generics, in particular because it is an issue that impacts us perhaps more so than some of the other Defendants because there are so many of us at this point in the litigation, and we are variously situated in terms of what we made and when we sold it, that if someone doesn't provide the specificity that was included in the short form complaints it does reek havoc on the structure that has been implemented.

So, I wanted to raise this issue for your Honor and invite the Plaintiffs to engage with us and others and Special Master Dodge to see if we can come up with a procedure to deal with this.

THE COURT: I appreciate it, I am glad to hear from

you. I thank you for your work. It is not easy given how many generics have been named at this point, so I am very appreciative of your role, your leadership, and raising this important issue.

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I am pleased to hear that you are recognizing them, but not in great numbers, but then again you are understanding that more short form complaints are being filed and you are trying to catch this on the front end before it becomes a major problem for all Defendants, including the generics, particularly in light of the Court's pronouncements in PTO 24 and emphasis here today about discouraging, for all of the reasons I have articulated, motion practice.

I take Mr. Pulaski's and Ms. Finken's comments as being amenable and consistent with your vision of wanting to have a process to work it out. I would follow up on what he has very clearly articulated as sending, and indicating to your constituency, so to speak, to send an email to Mr. Pulaski and copy Special Master Dodge and refine that process if you think something different or above and beyond what Ms. Finken and Mr. Pulaski have outlined, but I heard them loud and clear to say their lines are open, they want to hear from you.

They are no more interested in having deficient complaints, whether it be in the court file or claims in the registry, than the Defendants are.

So, I think everyone is on the same page. Let's let

the process work, that is the sort of let's not run to the Court with a motion yet. I realize, as I said from the outset, if processes don't work at the end of the day after considered effort and dedication and diligence, the Court can revisit what the proper process is.

But let's let this process play out, whether it's the one that's roughly outlined by Mr. Pulaski, or if you have any refinements to that within the confines and the parameters of the Court orders thus far, including PTO 24, I trust you have already spoken with him and will continue to do so, and the other generic manufacturers through their counsel would as well.

In a timely fashion, if parties are not supposed to be in a case, and information is incorrect or deficient it will be fixed and/or the party will be dismissed.

I think I heard, unless you heard anything differently -- although I understand it is very important for you to point this out to the Court because now you have seen in real time that there have been some deficiencies, that this is not a hypothetical conjectural issue, it is a real issue and needs to be addressed.

So, are you satisfied with what you have heard as to the process in place, that it be given a try and work collaboratively with Plaintiffs' counsel on behalf of your constituents to work through these deficiencies?

MR. YOO: Yes, your Honor, we are certainly supportive of the plans to work together to sort out issues regarding the registry and the Census Plus forms.

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I think this is a connected issue, but a slightly different issue, and I would be happy to engage with Mr. Pulaski and Ms. Finken or others and address this issue in connection with the ongoing discussions they are having with Mr. Petrosinelli.

THE COURT: Okay. I do appreciate they are different in that one is in the registry and one is a claim and one is an actual complaint in the court docket, but I sense that the process can be similar in terms of pointing out where there are deficiencies and trying to work through them.

So, I appreciate the point, but hope that the process will work, or at a minimum, that everyone will be patient in giving it a try for some considered period of time over the next, as Mr. Petrosinelli said, this is — although primarily there was a focus on the registry, but consistent with that, over the next 35, 45 days, 60 days, until we get to either another status conference, or even before then, that there is an ongoing dialogue about this issue and see whether the Plaintiffs can sufficiently address the concerns that some of the Defendants may have when they see deficiencies in the actual short form complaint that is filed.

MR. YOO: Yes, your Honor, we are happy to provide our

input on this issue as they have their discussion on the other issue. I think we are on the same page, I think this is part of the same process, and I too am hopeful that the process will resolve this issue.

THE COURT: Okay, terrific. Let me just see if there were any other matters on this issue before we segue into the next area of the agenda.

Okay. All right. I may see you again, Mr. Yoo, when we return to some issues that bear on discovery and I know we will be speaking about discovery and the status of discovery. I think for now, at least as relates to your comments on short form complaints, I appreciate it, thank you very much.

MR. YOO: Thank you, your Honor.

THE COURT: Okay. Next on the agenda is the topic of the Master/Consolidated Complaints.

As I indicated, among the many orders that were issued since the last status conference, there was an order setting a case management schedule, and with that was a deadline for the filing of the complaints — actually the deadline for filing the complaints was addressed at the last status conference, but it is memorialized in the order.

We have since seen the filings, we have three filings. We have personal injury, a class, and a third party payor complaint, and I understand that we will have, let's see, Mr. Cheffo and Mr. Agneshwar and Mr. Gilbert speak about some of

the issues that are related to the filing of the complaints, and as I understand it, perhaps the first issue you want to address with the Court is the foreign Defendants and personal jurisdiction issues.

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I know that we did speak about this at the last status conference, but I would like to get an update of where you are in the exchange of information and resolution of issues with respect to foreign Defendants.

Some of the questions I have are: Are you anticipating being able to work out many or most of the personal jurisdiction issues? Do you anticipate much motion practice in this area or is it too early to tell? What more do the parties need to do to try to work through these issues without motion practice? And is there anything the Court can do to assist the parties in the process?

I am just laying out my questions right at the outset and perhaps they can guide you in your comments on the first subtopic of master/consolidated complaints.

MR. GILBERT: Thank you, your Honor, Robert Gilbert, colead counsel on behalf of the Plaintiffs. Mr. Dearman and Mr. Keller will be joining us as well, they will be addressing a topic later that is part of this discussion involving the consolidated class complaints.

I am going to address now the issue of the four Defendants and personal jurisdiction that you just highlighted,

as well as I understand the Court was interested in a primer on the issue of service under the Hague Convention, so I prepared that as well.

THE COURT: Okay.

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MR. GILBERT: First, before I talk about the issue of the foreign Defendants, let me just say one thing.

I would like to take a moment -- I know you thanked a lot of the Court staff earlier. There is one particular branch of the Court staff that I would like to recognize at this point in time in addition to those you did, and that is the Clerk's Office, which has been tremendous in providing assistance to all of us thus far in the MDL, in particular Ms. Maria Cruz, the MDL clerk. As we acknowledged in Docket Entry 903, Ms. Cruz and other members of the Clerk's Office have been extremely helpful to counsel dealing with the multitude of filings, the issuance of summons, and a myriad of other issues.

First, before we talk about foreign Defendants, or non U.S. Defendants, I would like to give you just a very quick update on the status of service on the U.S. based Defendants.

I know that you were provided -- or I believe you were provided yesterday with a pretty detailed spreadsheet by liaison counsel for the Plaintiffs and for the Defense that everybody agreed upon.

The one thing missing right now from that spreadsheet, which will be updated early next week for you, are the status

of actual service on the Defendants.

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I am pleased to report as of yesterday, with regard to the U.S. based Defendants, that 89 of those U.S. based Defendants have been served, and for the other seven U.S. based Defendants those summons and complaints are out for service, and I expect that by early next week, barring an unusual occurrence, the remaining seven will have been served as well. So, almost all of the U.S. based Defendants have already been served with the summons and the three complaints that were filed on June 22nd.

With regard to the non U.S. Defendants, I may refer to them as foreign Defendants, the status of service right now is that two of the non U.S. Defendants have already been served as of yesterday. Those are the two Defendants that are based in Canada. Two other non U.S. based Defendants are pending service in the United Kingdom.

I will address this a little bit further in just a moment. We are in some detailed discussions with counsel for three other -- three non U.S. based Defendants regarding not only service, but the bigger picture of potential dismissal without prejudice of those foreign Defendants from the litigation.

In addition to what I have just reported, I have sent out emails on behalf of colead counsel for the Plaintiffs to Defense counsel who filed notices of appearance in the case on

behalf of U.S. based Defendants where we know that there is a foreign affiliate. In those emails that were sent out we have requested that those U.S. based Defendants and their counsel agree to accept service on behalf of the foreign Defendants in consultation with them, and that they also contact us if they are interested in exploring and engaging in the same type of discussions that I referenced just a moment ago with regard to the potential dismissal of overseas Defendants from the litigation.

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Thus far, I have not heard from any additional counsel to whom I directed those emails other than the three I mentioned already with whom we are already engaged in discussions. We are hopeful that we will hear from some or all of them in coming days. We have reiterated to them that acceptance of service does not constitute a waiver of any right to assert personal jurisdiction or venue, so that really shouldn't be a stumbling block here, it is just whether they and their overseas clients are willing to accept service or make us go through some additional process which I am going to address in just a second.

Excuse me. Sorry about that.

THE COURT: That's okay.

MR. GILBERT: Finally, there are nine non U.S. based

Defendants where we do not have any corresponding U.S. based

Defendant where counsel has already filed a notice of

appearance, so we technically don't have anybody to communicate with yet. I think one more notice of appearance may have been filed yesterday, so my nine number may go down to eight.

Those are overseas Defendants where to date a notice of appearance has not yet been filed by a corresponding U.S. based Defendant, so we have not been able to send the type of email that I alluded to a moment ago asking them to, A, accept service of process and, B, contact us if they are interested in having a meaningful conversation regarding potential dismissal without prejudice.

THE COURT: How many have you sent emails to whom you have not heard back from yet?

MR. GILBERT: 13.

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THE COURT: When were the emails sent?

MR. GILBERT: The emails were sent on Monday of this week. A couple of them acknowledged receipt of the email and indicated that they would be speaking with their respective clients, but we haven't received any emails either saying no, we will not accept service, or yes, we will accept service.

THE COURT: Are you at liberty to share the kind of information that you were able to or in the process of obtaining from the three who you had been considering dismissing without prejudice, what the information looks like that could persuade Plaintiffs to dismiss without prejudice?

MR. GILBERT: I am happy to discuss it at a high

level, and by the way, I have communicated that in these emails that have gone out. So, each of these Defense counsel know what the overarching principles are that we have enunciated that have to be part of this conversation, and those principles are, number one, an agreement for tolling under PTO 15 with respect to the foreign Defendant so that if we dismiss them without prejudice, they would be subject to tolling if we need to add them back in later on.

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Number two, adequate assurances that the U.S. based subsidiary or affiliate are fully capable financially of satisfying any eventual settlement or final judgment that may be entered in this case.

And number three, which is extremely important to us, that the discovery that is served on the U.S. based subsidiaries will be deemed to encompass the foreign — the overseas parents or affiliates such that the discovery responses would include the production of documents through the U.S. based Defendant from the foreign affiliate, as well as the production and availability of witnesses from the foreign entity that we could take depositions of during the course of the case.

There was a fourth pillar that I am not remembering right at this moment, but I will look for it when we take a break.

THE COURT: Are you envisioning this in the form of an

affidavit?

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MR. GILBERT: We are envisioning -- with regard to the overall agreements, we are envisioning them in the form of formal agreements, signed agreements that would be signed by both the overseas and the U.S. based entities that would likely be filed in the court, or certainly, if the stipulation for dismissal does not recite all of these terms clearly on its face, there would be a written agreement that would back up that stipulation that could be filed in the event it became necessary in the future.

THE COURT: Likewise, in the three instances where you are engaging in discussions, are you also receiving and/or receptive to receiving information from the Defendants and/or have they been willing to provide information as to both whether they are interested in entering into this agreement, but also in addition, reasons why they don't believe the Court has jurisdiction over those entities? In other words, are you evaluating that information as well that's being provided to you?

MR. GILBERT: We haven't gone into great detail in the conversations about why an overseas Defendant feels that they are not subject to this Court's personal jurisdiction. They obviously make that point as part of their discussions.

For purposes of our conversation, we accept their representation that they believe they are not subject to

personal jurisdiction, and we in turn believe that we can hale them into the Courts of the United States and subject them to personal jurisdiction in one form or another.

So, we haven't delved in detail into the facts about why they don't believe they are subject.

THE COURT: Okay.

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MR. GILBERT: So, as the Court knows, there are a multitude of overseas Defendants. There are one or two Defendants overseas from a myriad of countries, Canada, Germany, France, the United Kingdom, as I mentioned before, Ireland, Israel, Mexico, Switzerland and Singapore, and by far the most overseas Defendants come from India. There are 15 Defendants based in India, which brings me, if the Court would like me to do it now, to our discussion about a primer on the Hague Service Convention, or perhaps you want to hear first from Mr. Cheffo on where we are on the points I have already covered before I talk about the primer. I am at your leisure.

THE COURT: Thank you. Sure. Let's hear from Mr. Cheffo to just followup on the conversation that began already. And then, Mr. Agneshwar, I don't know if you are going to speak on this issue as well, but feel free --

MR. CHEFFO: I think Anand and I were going to maybe just tag team this a bit.

THE COURT: Okay.

MR. CHEFFO: I can just give a very brief overview of

where we are at a high level because GSK is one of the three, I think that's fair to say, and then Mr. Agneshwar may want to talk more broadly.

I think your Honor always asks kind of the right questions here, right, which is kind of where are we, what are some of the issues, is it too early, how can we differentiate, and how can we move past this. What I would say, kind of maybe being a little glass half full, is for some of these issues I think there are reasonable pathways, hopefully, working through them. I would say that we have to be practical, that it is not one size fits all.

For example, you know, as we just heard, as Mr. Gilbert just said, if you are kind of a member of a corporate group, right, and you have GSK, for example, or one of the others who is a Defendant who may have a foreign parent entity or related entity, that may be different, right, than if you are completely a foreign company, right, and may have different objectives, without getting into all of the issues.

So, for example, Plaintiffs are interested in getting some discovery and showing there is some kind of viability of the entities right, and there is some easier way to kind of effect process. From the Defendants' perspective, they are interested in not kind of having their potentially out of country or foreign entities subject to discovery, things that are not appropriate, not having setting precedent for

jurisdictional issues. That is why I think it lends itself to some kind of ability to narrow it as Mr. Gilbert said.

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You might say, well, we are going to voluntarily produce X, Y, and Z discovery if you won't officially name us, so it takes a lot of their issues off the table because. As I think you will hear from Anand and Mr. Gilbert, there are clearly — I think were we to collectively brief this, I think the Hague is there for a purpose, it requires certain rules to be followed, and frankly, they are not as easy as serving under the Federal rules typically.

So, I think what you will hear is you may hear different things from different kind of Defendants on this, right. I think, as Mr. Gilbert said, this essentially puts aside the issue of whether we would actually win a personal jurisdiction motion or not, and as your Honor is saying, we don't need to fight every single battle, we don't need to brief every single motion.

If one of the issues is we think it would be right, but we have to go through all of these different hurdles and we would ultimately just agree to produce some discovery, even if they were to do it through the Hague, maybe we can get there in a more amicable way and just give them what they want largely, and maybe they will kind of understand our concerns largely and reach kind of agreement.

What I can't speak to is -- and I am going to turn it

over to Mr. Agneshwar, he may have some comments -- is there may be Defendants here who are just differently situated.

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If you are kind of just of a India or Israel company who doesn't have kind of operations here, that may be a different kind of set of facts and circumstances that — those may be things your Honor may ultimately have to — I don't represent those folks, I haven't been in those conversations, but I can see it differently.

I think where there is probably a little more room for immediate negotiation is when you have this kind of mix of U.S. based entities with related foreign entities.

So, hopefully that answers some of your questions, your Honor, and what I would say is we are literally real time, you know, Bobby and our team have been talking, there is a phone call on Monday to kind of nail these down, and hopefully, your Honor, if we need to, the Special Master, God will get involved in this, and ultimately, if we have to address these, we will, but I think we are trying to find a pathway to avoid that.

With your Honor's permission, I was going to kick it over to Anand and he can add something as well.

THE COURT: Sure. Thank you.

MR. AGNESHWAR: Good morning, your Honor, nice to be before you again.

Let me just start by saying I represent Sanofi, and

Sanofi has an indirect parent company that is headquartered in France, and my prediction is — I agree with Mark, these are very case specific issues as to each Defendant, but we have been kind of going back and forth with email proposals for the last few days, so I don't think that is going to be an issue at the end of the day.

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I will say this: Why does this take such a detailed negotiation like this? It is corporate separateness. So, while there is a Sanofi U.S. that holds the NDA for Zantac today, that liaises with the FDA, that is ultimately responsible should anything go wrong, and that is the entity that the FDA comes to if there's any problem, that, in our view, is the entity that is responsible for the marketing of the drug in the United States. The indirect parent company, Sanofi France, there is collaboration, they are responsible for global strategy, but ultimately it is a separate company.

It is really important to U.S. clients like ours that have affiliate foreign companies to make sure that principle of corporate separateness is respected. That is why, typically, you don't just allow the U.S. affiliate to say, oh, we will start accepting service for the foreign company and the like, because you want to keep those principles intact, not just for this litigation, but for future cases, for SEC filings, for everything.

That being said, the rules on jurisdiction are you

can — they are complicated, they are changing from the Supreme Court. There is stream of commerce jurisdiction, there is the recent Bristol-Myers case on specific jurisdiction. There is arguments in favor of jurisdiction and there's arguments against jurisdiction over a foreign company and it is often very fact specific, depending on how much involvement there was in the U.S., where it was targeted, and that sort of thing.

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So, I think that more than the Hague Convention is what is driving these discussions because we know -- Sanofi France knows that if it files a motion it could win, but it could also lose, and the Plaintiffs know that if they litigate that motion, they might win and they might lose, so that's what is driving us together.

The Hague Convention itself, at least for the countries that have joined it, which I think is about 70 countries -- I don't know whether India or Singapore are signatories to it. But for France it is pretty straightforward; you serve your papers to a central depository in France and then they effectuate service and provide proof of service. It ordinarily takes about 45 to 60 days, it is not this long, drawn out process. And the Federal rules actually even provide if it does take an inordinately long time, the Court can actually order a different method of service.

I don't think it is that so much that is driving these discussions, it is the issues about jurisdiction and figuring

that if we can get the Plaintiffs what they want in terms of putting the factual story together, which will in some cases involve collaboration with a foreign parent, and get that discovery to them and satisfy them that they are not going to face any unnecessary hurdles, and they can be satisfied that they can litigate their case effectively, then this should be able to be resolved.

THE COURT: Resolved within the time frame of -- let's see. The PTO 30 had the Motions to Dismiss coming in on August 23rd, so --

MR. GILBERT: Yes, your Honor.

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THE COURT: Is that a comfortable deadline everyone can work with on at least that issue?

MR. AGNESHWAR: Again, I think every Defendant is situated differently, and I can't speak for these companies that are situated purely abroad without an American affiliate, but for us, I think that's more than enough time to fish or cut bait on this issue.

THE COURT: Okay. Mr. Gilbert, how many of the Defendants are just foreign entities?

MR. GILBERT: Judge, as Mr. Cheffo and Mr. Agneshwar were speaking I was trying to recall that number. I don't know the exact number that are purely overseas without any U.S. based affiliate or subsidiary, but I can get that number relatively quickly.

I would agree with what Mr. Cheffo and Mr. Agneshwar said in the sense that it is very fact specific, and in those instances where there is an overseas entity without a corresponding U.S. based affiliate or subsidiary, it is a more difficult problem because in most of those instances the overseas entity is the holder of the ANDA. That is why it is essential to us to have that entity in the case.

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In some other instances you have overseas entities as well as U.S. affiliates or subsidiaries that both hold ANDAs, or even if the overseas entity did not hold an ANDA, it was involved, in our view, in a very significant and substantial way in some aspect of the manufacture, marketing, sale, or scientific research relating to the claims that are being brought in this case.

I didn't want to identify by name any of the parties ahead of time because I didn't think it was my place to do so, but since Mr. Cheffo and Mr. Agneshwar both acknowledged that we were speaking with them, I can say we are engaged in good faith discussions with both of them. I am reasonably optimistic that we may be able to reach an agreement.

I found my email that was sent out to all of the 13

Defense counsel that laid out the six tenets, if you will, the six elements that are key to us of any such agreement, and with the Court's permission, I will just recite them for the record.

Number one is dismissal without prejudice of the

related non U.S. based Defendant.

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Two, tolling of Statutes of Limitation per PTO 15 for both the U.S. based and the non U.S. based Defendants.

Three, a stipulation that U.S. based subsidiary or affiliate is the proper party and interest for purposes of all claims asserted against the non U.S. based Defendant in the litigation.

Four, production of relevant documents and witnesses from the non U.S. based Defendant as part of our discovery directed to the U.S. based subsidiary or affiliate.

Five, demonstration of financial ability of the U.S. based subsidiary or affiliate to satisfy any settlement or judgment, or an indemnity agreement along with a consent to jurisdiction from the non U.S. based Defendant for the limited purpose of enforcing any settlement or judgment that may be entered down the road.

And lastly, our right to join or add back into this litigation the non U.S. based Defendant in the future without opposition from either the U.S. based subsidiary or the foreign affiliate and the acceptance of service without waiver of personal jurisdiction or venue Defendants in the event that becomes necessary.

Those are the foundational elements that we have communicated to all of these counsel, including the two colleagues that you heard from already, and as I said and they

acknowledge, we are engaged in good faith discussions with them, and as you can imagine, every conversation is somewhat unique.

I would say that this is probably the perfect segue to the discussion a little bit about the Hague Service Convention. If you'd like, I am happy to give a relatively short primer on that for the Court's benefit.

THE COURT: Yes. I am just mindful of the time.

So, why don't we have you, yes, give a short -- a very short primer, and then I may check with our court reporter to ensure that we are doing okay, and she does not need a break.

Let's have you complete that before we get into another topic, and I will inquire.

MR. GILBERT: Sure. So, as the Court knows from prior decisions that you have actually entered, any primer on the Hague service issue starts with the recognition of two overarching principles. First, the underlying purpose of service of process, that is about giving the Defendant or interested party notice of the pendency of an action and the opportunity to respond.

The second overarching principle is the mandate of Rule 1 of the Rules of Civil Procedure to secure a just, speedy, and inexpensive determination of any action or proceeding. We need look no further than the Supreme Court's 1987 decision in Societe Nationale where it held that a rule of

first resort to the Hague Convention in all cases would be inconsistent with the overriding interests of the just, speedy, and inexpensive determination of litigation in our courts.

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Federal Rule 4(f) governs service of process outside the U.S. It provides that service may be made by means that include international agreements such as the Hague Service Convention, or, under 4(f)(3), by other means not prohibited by international agreement as the Court orders.

As then District Judge Rosenbaum held in the Abercrombie case back in 2014, Rule 4(f)(3) allows a District Court to order an alternate method of service to be effected upon foreign Defendants provided it is not prohibited by international agreement and is reasonably calculated to give notice to the Defendants.

An important point to keep in mind, and I think it is going to be the primary focus of any issues that come forward involving Hague service in this case, is Section 10 of the Hague Service Convention, and that is a provision where certain countries that became signatories — and by the way, in response to Mr. Agneshwar's point, I know India is in fact a signatory to the Hague Convention, I am not certain about Singapore.

Section 10 is a section of the Hague Convention that comes into play when we discuss alternate service, or service by alternate means, and Courts throughout the country have held

repeatedly that when a country has lodged an objection to alternative means of service set forth in Section 10, it is only those specific means that are identified in its objection that preclude alternate service and they do not represent a blanket objection to other forms of service such as email or publication. There are numerous Courts that have discussed this and we will address them in our papers should we need to file them.

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To Mr. Agneshwar's point, there is really no hierarchy under Rule 4(f) as to what type of service must be sought first, and in a case like this one where we have an 18-month discovery period which has already begun, getting service quickly and efficiently comports with Rule 1 of the Federal Rules and would allow this Court, upon a proper showing, to move forward in authorizing alternate service.

The Courts have held clearly in this district and elsewhere that the subsections under Rule 4(f) are not mutually exclusive and there is no indication they are meant to be read as a hierarchy and that alternate service under 4(f)(3) is not to be considered a last resort or extraordinary relief.

But what our Courts have held, dating back to 1950 with the Supreme Court's decision in Mullane, is that any method of service crafted by the District Court pursuant to 4(f)(3) must be reasonably calculated under all circumstances to apprise interested parties of the pendency of the action and

afford them an opportunity to present their objections.

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Many Courts in this circuit and elsewhere have found that email service is permissible and practical so long as the country where the Defendant is at home has not specifically objected to the use of email service as part of its Hague Service Convention agreement. This is particularly true when the international Defendant is a major international business that conducts substantial business by email and maintains well-kept web pages in English. Publication service has also been approved by Courts as well.

Lastly, I will say that Courts have frequently permitted alternate service on a U.S. subsidiary on behalf of a foreign corporation as an independent means of accomplishing service under Rule 4(f)(3) and/or under 4(e), which allows for service on a subsidiary or a local office, and we need only look to the Volkswagen work case from the Supreme Court in 1988, where it held that the Hague Service Convention need not be used to serve process on a foreign corporation when service can be made on a U.S. subsidiary with a sufficiently close relationship to the overseas parent.

And this is particularly true when the U.S. subsidiary is wholly owned by the foreign parent or is alleged to be the alter ego of the foreign parent.

In emails that I have sent out to these 13 Defense counsel, and hopefully be able to send out more in coming days

as we see notices of appearance filed, we have indicated to them that absent receiving their agreement by next Wednesday, July 13th, (sic) that they will waive service of the three complaints that we filed on June 22nd.

I told them, informed them that we intend to file a motion late next week seeking an order pursuant to Rule 4(f)(3) and 4(e) permitting alternate service on each foreign Defendant through various means that will be detailed in our service plan. We are confident the facts and applicable law will clearly support this Court's exercise of its sound discretion to grant that motion and order alternate service.

That is the conclusion of my primer on Hague Service Convention issues.

THE COURT: All right. Thank you very much.

Anyone that needed to respond before I move on to -well, before I check in with Ms. Stipes and move on to the next
subsection?

MR. CHEFFO: Literally 30 seconds, and this is one of my roles as the colead, so I don't really want to take on the issue here of arguing whether it is appropriate or not. You have heard both Mr. Agneshwar and I hope that we don't need to address these issues.

All I think I would say is it would probably not surprise you, were this needed to be briefed, there is probably a difference of view and other case law that might kind of bear

upon this issue in terms of whether alternate service is or is not proper. That is kind of not my issue right now to decide personally and I am not here to argue it, but I think I would just be remiss if it was heard that we kind of agreed with all of the issues and the case law cited.

So, I just note that for your Honor.

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MR. AGNESHWAR: Your Honor, if I can just supplement that. I would say this has recently been discussed in a case by Judge Moreno called International Design Corp. versus Qingdao Seaforest Hair Products. It took, I think, a little bit of a different view about when alternative service is appropriate. Again, it is not my issue either, but I also feel that I just need to say that as we are the only two spokespeople on the Defense side.

THE COURT: Got it. Well, I appreciate the presentation, and like anything else I usually end with, please talk about it, meet and confer about all of these issues generally, foreign Defendants and service, and what agreements can be reached, if any, and also this topic of alternative service before any motions are filed relating to that so that there is a full breadth of understanding of the issues, sharing of the case law, and perhaps a meeting of the mind that might obviate the need for any motion practice or extensive motion practice.

But if that can't be accomplished, I understand where

the Plaintiffs may feel they need to go on that.

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Can I check in with Ms. Stipes?

I appreciate the presentations.

I am going to go to subsection B of the agenda, part three, which is the PI Master Complaint, and Mr. Agneshwar and maybe Mr. Keller should be joining us I understand, if I am reading — there is Mr. Keller. Good afternoon. Yes, we have crossed afternoon, it is 12:01.

I do understand, obviously I have read it a couple of times, the PI Master Complaint was filed since our last conference. So, I would invite any comments by Mr. Agneshwar on that. I would invite Mr. Keller to make any comments as well.

MR. AGNESHWAR: Sure. I am happy to go first since we will be moving in six weeks or so, if that makes sense.

THE COURT: Sure.

MR. AGNESHWAR: So, with the caveat, your Honor, that this is a long complex complaint with a lot of allegations against a lot of Defendants over a long period of time, that we are still vetting it and trying to figure out what we are going to move on, what is appropriate for a Motion to Dismiss, what is appropriate for some other process, what we might just want to shelve for now.

With that caveat, I can say this: There are three issues that really jump out at us from the complaint that we

are discussing the possibility of Motions to Dismiss. I don't think this is going to be a surprise based on those initial presentations we did at the last CMC, but these are preemption, shotgun pleading issues, and innovator liability.

I am going to be very brief. This is not the opportunity to argue the issue, I am just going to point out what the arguments that we are looking at are.

So, the central issue in a preemption analysis, to take that issue first, is whether a company could have done something unilaterally without seeking the FDA's prior approval. That is essentially 101 on preemption. If you can do something unilaterally, if you can change the design, if you can change the warning, maybe there is a case there, but if you can't, the Supreme Court has held in Mensing and Bartlett, two significant cases that will be at issue, that there is preemption.

So, there are three causes of action in the complaint, design defect, failure to warn, and manufacturing defect. If you start with design defect, the theory behind design defect is there is something inherently wrong with the Ranitidine molecule that should have been fixed.

On that issue, I think it is our position, your

Honor -- and I am speaking here on behalf of all the classes of

Defendants, the brandeds, the generics, the retailers, the

repackagers, the distributors -- none of these companies can

change the design of the molecule. The FDA approves a particular molecule the way it is and you can't just unilaterally change it. You can get a new drug approved, but you can't change that.

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So, it would be our view that under design defect that would be preempted as to all Defendants.

So, that moves us to failure to warn, and on this issue I think the branded companies are situated a little bit differently than all the other companies, but essentially the issue is still the same.

Could a company have unilaterally changed the warnings without getting FDA approval? If they could do that unilaterally, and there is a provision called CBE that you heard about last time that allows the NDA holder to do it under certain circumstances, then there is the potential for liability, but if you couldn't, the Supreme Court has said there is no liability.

On failure to warn, it seems to us that the only category of Defendants that could possibly be liable under the failure to warn theory are the NDA holders for the product because they are the only companies that could utilize the CBE process to change the label. So, that would mean that failure to warn claims against generics, retailers, distributors, repackagers, and anybody else downstream on the distribution chain, claims against them would be preempted.

For the brand manufacturers, the regulations allow changes being effected when there is new information about a product that comes out after the NDA is approved, and that is the issue that we are looking through the complaint and evaluating whether we have arguments on preemption there. We are still going through that analysis, but if we do, that is the argument we would be making.

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Then the third category is manufacturing defect, and I think this really applies more so to retailers and distributors and everybody downstream below the manufacturers, they just can't be liable for a manufacturing defect because they didn't manufacture the product.

So, on preemption, again without committing to anybody filing any particular motion, that is in broad strokes the types of arguments we are looking at developing and thinking about timing.

Shotgun pleading, this is a complaint where there is a ton of liability allegations that are made against every single Defendant and every category of Defendant. As the Court knows, since we talked about it a little bit today, and the census process is designed to address some of these, different companies had different roles, different companies had the product at different times. GSK, for example, was there at the beginning, Sanofi is here at the end, and there are a number of other companies that are in between, and that is just for the

brandeds. For the generics, the retailers, and distributors it is the same sort of thing.

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The allegations of the complaint are in broad strokes against all the companies, and in the Eleventh Circuit shotgun pleadings like that are disfavored. So, we are looking at whether there are potential avenues through a Motion to Dismiss process to sort of get more clarity as to which allegations are relevant as against who.

Just to give you one example just based on my client, my client got this product in 2017, so anything that happened before its watch could not be noticed as against Sanofi. So that is the -- or if another company, Pfizer, had the product for a period of time in the early 2000's, a study that came out in 2010 can't be noticed against Pfizer. That is the type of thing we are looking at.

That is going to matter as we go through discovery, as we think about who the relevant witnesses are for which company, how many witnesses from each company, and the like.

That is issue number two.

Issue number three is this issue of innovator liability. This issue is really framed like this, if generic companies can't be liable because you can't have claims against them because they don't have the authority to change the label and the design, the Plaintiffs have tried to say in many states, well, then the brand manufacturer who has the ability

to change the label -- to change the label -- nobody can change the design -- should be liable under a failure to warn context even if the Plaintiff has never taken that product.

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That theory -- because product ID is kind of an elementary element of tort law, that theory has been rejected by the vast majority of states. I believe there are only two states that have accepted some form of innovator liability. It is not completely clear whether the Plaintiffs here are trying to make the brand manufacturers liable for injuries related to that generic use of the drug, but that is another issue that the companies are looking at right now.

In broad strokes, your Honor, those are the three substantive areas that we are looking to attack the complaint on. I would be happy to answer any additional questions you have about that.

THE COURT: Thank you very much.

Mr. Keller, did you want to make any comments?

MR. KELLER: Sure, your Honor. First, for Ms. Stipes' benefit, it is Ashley Keller from Keller Lenkner on behalf of the Plaintiffs.

I am a little bit nonplussed by my friend's comments because I was not prepared to talk about the substance of any motion practice. This is the first I am hearing from Mr. Agneshwar, or anybody on the Defense side, of these sorts of objections to the Master personal injury complaint.

Of course, I am not surprised that they think they have arguments that would favor dismissal, but the last time the Master personal injury came up was in a joking way. We had a long call going into the Independence Day holiday on July 2nd, and the only thing was said about the Master personal injury complaint was Mr. McGlamry making a joke saying, so you all didn't talk about the Master PI complaint so I assume you agree to liability, and nobody said anything.

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Of course they don't agree to liability. You just heard that from Mr. Agneshwar. We don't begrudge them their opportunity to file a 12(b)(6) or any other Rule 12 motions. That is contemplated by this Court's pretrial order.

What I thought we would be were talking about here on this CMC was not their preview of their arguments, which I am not going to respond to, they can put it in their papers, but more page limits, how we want to structure it because there are different categories of Defendants. We, of course, agree that they shouldn't have to stick to the local rules and only have 20 pages, but we were hoping that we wouldn't also be briefing War and Peace on a Tolstoy novel just given all of the complexities.

So, the fact that they are potentially limiting themselves to three categories of arguments I hope means that we can have a manageable process here and that is sort of what I am prepared to discuss. I don't think it is appropriate at

this juncture for me to preview our opposition to preemption and the Rule 8 issues and innovator liability.

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So, from my vantage point, I thought this was going to be a little bit more about the mechanics of the process as opposed to the substance of their motion. Of course, again, they can say whatever they want in their papers, they have a right to do that, and we will oppose at the appropriate time.

THE COURT: Well, the order 30 did talk about, to some extent, a process whereby the motions would be consolidated in part, delineated by the nature of the Defendants, as more fully set forth in the procedures for master pleadings. It is true that that order did not go into detail about page limits, and things of that nature.

I would like the parties to have the opportunity to talk about that, and certainly I am not expecting that you provide me today with any proposals or agreement. If you haven't spoken about it, I would encourage you to do so.

I would think to some extent, as Mr. Keller has realized, that maybe the more you understand, and so to that extent, I take it as helpful that Mr. Agneshwar outlined three buckets, three areas. At the initial status conference there was presentation on preemption. I believe there was on innovator liability as well. There really couldn't have been on shotgun pleading because there had not been a pleading at that point.

So, I would say that the parties should meet and confer and discuss more about these issues. I think it can only help. You may ultimately respectfully disagree, particularly if you have different views on the law as it relates to, let's say, preemption and innovator liability, and so that may just have to be hashed out in the motion practice. I understand that.

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I would think shotgun pleading would be a ripe area, however, for discussion, and that is an area that comes up a lot even in non MDLs. I try to catch those early, either when they are raised in a formal motion or even before, and encourage the parties to meet and confer about it. Often times my experience, although, again, not having prejudged this complaint in any way or any motions, is that if an allegation is shotgun pleading and it lends itself to any kind of a granting of a motion, whether it is in full or in part, based on that argument, it often, if not always, is without prejudice and you are back to the drawing board repleading.

I say that because Judge Reinhart and I work very closely on this issue. We like to save parties time of full briefing on issues like, let's say, shotgun pleading, and I am just using it as an example because it came up, and see if there can't be a meeting of the minds.

I would think that with all of the discussion preceding this part of the agenda relating to getting clarity

and more information about which Defendants did what, when, where, how, the more expeditious that process can be undertaken would behoove everyone.

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It would help Plaintiffs so that if certain allegations just don't have a basis in the information that is being provided, and that is what Defense means hypothetically about shotgun pleading, that could be addressed and there could be some agreement on an amendment.

Again, this is very just general, nonjudgmental commentary based on the Court's experience with other pleadings, albeit ones that have not been in the context of MDL, when issues of shotgun pleading come up. So, I would think, at a minimum, that is an area that is ripe for discussion and lends itself to the very issues that preceded this discussion on exchange of information and clarity.

I understood the Plaintiffs not wanting to have claims and Defendants in the case that don't belong, and Defendants have a similar view. So, there was sort of an agreement on that.

I think some of the information that hopefully is coming to light both through the registry and also through Ms. Finken's presentation of what information she thinks would be very helpful, and I did not necessarily hear any disagreement on that, will go a long way towards addressing it.

I don't think we really need to say anything more, at

least I don't, unless you all think you need to, and I am happy to entertain at a different time any proposals regarding the mechanics of motion practice because clearly it is coming, it is just on what issues, and what it is going to look like.

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So, talk about it. Again, I think the meet and confer will lend itself nicely. I want you to have enough time -- well, the time limit is already set -- but enough pages to do what you need to do. Sometimes shorter is better, like just get the Court what the Court needs and don't have the Court get bogged down on what it doesn't need so I can focus and make the right decision, because you all want me to make the right decision.

Shall we leave the PI complaint on that note or does anyone feel anything more needs to be said on that?

MR. KELLER: Your honor, can I say something really quickly on the issue of shotgun pleadings? We are very happy to meet and confer with our friends on the other side in keeping with the spirit of the discussion we just had.

The only point I would make as a distinction between the Master PI Complaint and the class complaint, is that the Master PI complaint by itself is not an operative pleading, you need the short form complaint added to it. Per your previous discussion with Ms. Finken and Mr. Pulaski, we are working extremely hard to ensure that the short complaints are accurate.

So, one of the concerns I know Defendants have with shotgun pleadings is they don't know which Defendants are subject to particular allegations or claims.

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I think the short form complaints are going to go some ways to answering that because only particular Defendants are going to be named when you have actual Plaintiffs who are identifying themselves, but we can continue the meet and confer process and see if some of the related issues can be resolved to the Defendants' satisfaction.

THE COURT: Right. I would hope so. So, the challenge, I guess, is you have this August 23rd date set by order, and so, you know, you kind of work backwards from there. It obviously takes time to prepare the motion, but you don't want to be preparing motions if you don't need to, if it could be resolved. So, to me, that is like a critical issue.

The law is the law, you are going to do your excellent briefing, I have no doubt, on legal issues like innovator liability and preemption. But on the shotgun, I would just say really work very hard with that deadline in mind and maybe there is room for discussion about kind of an ongoing process on that. I kind of see that as its own bucket.

Let's see. It has been such a good conference so far in terms of the positivity of -- and consensus on sort of the criticality of vetting and narrowing and winnowing, and I think that just plays right into the term "shotgun" as used in the

context of a potential motion to dismiss. I encourage you to go forth with all of the good positive comments that you are echoing yourselves on at least that issue. Okay?

MS. KELLER: Thank you, your Honor.

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MR. AGNESHWAR: Absolutely, your Honor. I am happy to reach out to Mr. Keller and talk to him about these issues as well as the page limits and things like that.

THE COURT: Perfect. Okay. Terrific. Let us move on, then, to the consolidated class complaint. I think Mr. Bayman, Mr. Cheffo, Mr. Gilbert, Mr. Dearman and Mr. Keller on the agenda. We have more of you so be extra careful about stating your name before you speak.

I assure you, Pauline, we are more than 50 percent through the agenda, and I think it is going to pick up from here.

What would you like to tell me? I think as we have it we want the Defense to go first and then Plaintiff's response? Is that how you had envisioned it?

MR. BAYMAN: Yes, your Honor. This is Andy Bayman from King and Spalding, counsel for Defendant Boehringer Ingelheim and one of the coleads.

Mr. Cheffo and I are going to split this presentation.

I am going to address some of the legal infirmities that we find, and he is going to talk about practical problems that we think have been created by these consolidated class action

complaints.

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We believe, your Honor, unlike the case with the personal injury complaint where a lot of that was worked out, frankly, in advance, the consolidated class action complaints as they currently stand are really unworkable, and are not good vehicles to fairly, expeditiously, and efficiently litigate the putative class actions.

Obviously, we recognize there is a significant degree of complexity that is unavoidable in MDL litigation, but we believe these complaints have actually compounded that complexity significantly. We think now is the opportune time to grapple with these procedural infirmities rather than later so that the Defendants have clarity on certain fundamental issues in the case.

Your Honor actually addressed some of them a minute ago, and those issues would be which Plaintiff has claims against which Defendants, in which jurisdiction would these claims be brought outside of the MDL, what happens to these cases and claims when they get remanded, and what happens to the previously filed class action complaint whose Plaintiffs are not included in the consolidated class action complaints.

As Mr. Keller mentioned, last Thursday we had a lengthy meet and confer between the class action team on the Plaintiff side and on the Defense side to raise these concerns and I think we had a very spirited discussion knowing that the

CMC was coming up. We would like to get your Honor's guidance on a few issues and then hopefully, in working with Special Master Dodge and with the Plaintiffs, we may be in a position to resolve some of these issues that we currently face and that we are grappling with.

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Your Honor, I just want to make two overall points.

We have a number of concerns about the consolidated class action complaints, but I only really want to touch two issues, one of which that has already been mentioned in the context of personal injury complaints, but I think is actually even more glaring here, is that these consolidated class action complaints run afoul of the longstanding precedent in the Eleventh Circuit prohibiting shotgun pleadings.

They fail to accomplish really what is the most basic requirement of a complaint, to put each of the 94 Defendants on notice of the reasons why each of the 238 Plaintiffs thinks he or she has a right to sue them.

Secondly, your Honor, because the Master class action complaints are not true consolidations of previously filed actions, there is substantial uncertainty concerning what exactly they are, where they will go back once the MDL has closed, and what happens to the previously filed class actions. These Plaintiffs are not included in these consolidated complaints.

Your Honor, the consumer class action complaint,

Master complaint, is more than 1300 pages long and it contains more than 5900 paragraphs. The third party payor complaint is 190 pages long and it contains more than 675 paragraphs.

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The fundamental problem with these complaints is that they fail from one degree to another to give the Defendants adequate notice of the claims against them and the grounds upon which each claim rests. There is ample case law in the Eleventh Circuit on this, including some of your Honor's cases, including the Rodriguez versus Lawson case.

You may ask, well, how can it be that a 1300-page complaint doesn't give the Defendants adequate notice of the Plaintiffs' claims? The Master consumer class action complaint purports to bring 314 total counts on behalf of 238 named Plaintiffs against the 94 named Defendants. The vast majority of these claims, your Honor, over 250 counts, are asserted against all Defendants. The remaining claims are brought, at a minimum, against all brand name manufacture Defendants and all generic manufacture Defendants.

So, your Honor, every single named Plaintiff in the consumer class action Master complaint asserts multiple claims against every single Defendant. The problem with this, your Honor, is it is inconceivable that any named Plaintiff actually has claims against all the Defendants.

If each Plaintiff only brought a single claim against the Defendants, that would mean 238 named Plaintiffs times 94

Defendants, the Court would need to make 22,372 individualized determinations about whether a particular Plaintiff's claim may proceed against a particular defendant.

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This is not a true class action, your Honor; this is a set of claims brought by a group of individuals who have been improperly joined in one lawsuit.

Your Honor, at face class actions are individual actions, they are brought by individuals who claim they have been wronged by the Defendant, but purport to have representative claims.

In this case, your Honor, the Plaintiffs' claims do not and cannot arise out of the same transaction or occurrence.

One example, your Honor, just is the Plaintiff from the District of Columbia. The Plaintiff's complaint alleges at paragraph 48 that Plaintiff Kevin Nelson is a citizen of the District of Columbia, that the Plaintiff purchased and used Ranitidine containing products, including prescription Ranitidine tablets and capsules, in 2018 to treat acid reflux from MED LLC Pharmacy in Maryland. From these meager allegations the complaint raises five counts brought on behalf of the District of Columbia class against all the Defendants.

So, putting aside the first point, your Honor, that the lone D.C. named Plaintiff alleged that he purchased the product in Maryland, it is unclear from the complaint how this Plaintiff has any claims against any of the brand name

manufacturers or the generic manufacturers who sold only over-the-counter Ranitidine or Zantac products given that he claims to only have purchased prescription Ranitidine. Even if he alleged that he purchased over-the-counter Ranitidine or Zantac, given that he only alleged that he purchased the product in 2018, it is unclear how he could assert claims against predecessor NDA holders who no longer made the product in 2018.

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Plaintiffs also brought his claim against all 19 of the retailer Defendants even though the only pharmacy where he claims to have purchased Ranitidine products is this MED LLC Pharmacy. MED LLC Pharmacy, your Honor, is not even a Defendant in the case.

He also asserts these claims against all four distributor Defendants and all three repackager Defendants even though he alleges no facts whatsoever connecting his claims to any of these entities.

The only count brought on behalf of the D.C. class that is not asserted against all Defendants is Count 57 which is for a violation of the District of Columbia Consumer Protection Procedures Act, and that is brought against all brand name manufacture Defendants and all generic manufacture Defendants. Yet, the Plaintiff pleads no facts to identify which Defendant actually manufactured the Ranitidine he purchased.

So, in short, your Honor, while the D.C. named Plaintiff has brought claims against all 94 Defendants, not a single one of those Defendants has any grounds to know whether they have been properly sued by him as there are no facts alleged whatever connecting his alleged purchase to any of the Defendants, and we believe this violates the shotgun pleading rules, as well as Rule 8 and Rule 10, your Honor.

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This Court has previously quoted the Eleventh
Circuit's admonitions that experience teaches that unless cases
are pled clearly and precisely, issues are not joined,
discovery is not controlled, and the trial Court's docket
becomes unmanageable, the litigants suffer and society loses
confidence in the Court's overall ability to administer
justice.

We believe all those factors are present here and this is a classic shotgun complaint that is prohibited by clear Eleventh Circuit jurisprudence.

The second problem, your Honor, I wanted to highlight, and I will only touch this briefly, is Plaintiffs' decision to bring claims on behalf of named Plaintiffs who have not previously filed any actions anywhere.

Of the 238 named Plaintiffs, only 23 previously filed class action complaints that were transferred and made part of this MDL. Thus, your Honor, 215 of the named Plaintiffs apparently never filed a lawsuit in any form, not in the

Southern District of Florida nor anywhere else. Moreover, none of the named Plaintiffs in the third party payor complaint previously filed class action complaints that were transferred and made part of the MDL.

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Your Honor, as an initial matter, the parties never agreed to, nor did the Court permit a mechanism by which class action Plaintiffs as opposed to the personal injury Plaintiffs could direct file their claims into the MDL. The Court's pretrial order number 11 is clear that it applies only to personal injury claims brought by the Plaintiffs, and it also says no multi-Plaintiff complaints may be directly filed in MDL number 2924.

Nor did the parties agree, nor the Court permit

Plaintiffs to assert new class claims brought by putative class representatives who did not previously file a complaint in any jurisdiction. Those complaints also purport to bring claims against new Defendants who were not named in any previously filed action and have had no involvement whatsoever in the MDL.

The Plaintiffs have not offered any indication concerning how these consolidated complaints relate to the original class actions already pending in the MDL, whether they are consumed in the consolidated class complaint, what to do about the named Plaintiffs in the original class actions who are not named in any of these consolidated class actions.

And lastly, by combining the claims of all the

Plaintiffs from different states from all these Defendants from all over the country, and the world for that matter, into a single mass complaint Plaintiffs have created a jurisdictional mess, and it is unclear what will actually be remanded pursuant to Lexecon and where.

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Plaintiffs filed a jurisdictional statement after the Master complaints were filed, but that doesn't provide any answers either.

For example, even if the entire consolidated consumer class action complaint in its entirety was remanded to a Federal District Court where the claim could have been filed against one Defendant, a forum that has general jurisdiction over one of the Defendants, Plaintiffs don't explain how that forum could exercise jurisdiction over the 93 Defendants named in the consolidated complaint.

Your Honor, there is no Court in the country that would be able to exercise personal jurisdiction over the claims in either of these Master class action complaints as presently construed.

I will address for a minute, your Honor, a particular issue with respect to the third party payor complaint. That complaint is filed, your Honor, seeking moneys from health insurers that they paid in reimbursement for prescription Ranitidine products, yet the Plaintiffs have also included as Defendants in the third party payor complaint companies such as

Pfizer, such as Sanofi, such as Boehringer Ingelheim, for example, who sold only over-the-counter Ranitidine or Zantac.

The Plaintiffs have included these Defendants under a RICO theory and we believe the RICO theory, your Honor, is baseless. There is no hint of criminality, there's no suggestion that there is some 37-year pattern of racketeering supposedly perpetrated by a collection of 24 different entities whose business has been to develop medicines and sell medicines that help people. So, we believe the RICO claim is fatally flawed as the basis of -- their basis for nationwide jurisdiction, and we believe that claim fails.

We also believe, your Honor, that there is an express preemption defense for over-the-counter products under 21 USC 379, which bars various state law claims seeking economic damages, and we intend to address that. And there are other legal issues, your Honor, that we would address by way of motion practice, but that is the overall concern about the procedural infirmities, and now Mr. Cheffo is going to talk about the really practical problems that it poses.

THE COURT: Okay.

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MR. CHEFFO: Your Honor, Mark Cheffo for GSK. I am going to be pretty brief because Mr. Bayman covered really I think most of the waterfront, and I think some of these are kind of self-evident, if you will, issues that flow from Mr. Bayman's comments.

I think at the end of the day, right, we all want really what your Honor has been articulating all along, right. We could essentially just have this complaint and we could file and ask your Honor for 500 pages of briefing to try to figure out and have 90 different Defendants, each one saying I don't understand where the claims are, you don't have allegations, it is not a properly pleaded complaint, it's shotgun, Twombly, Iqbal.

That can be done, but that doesn't really seem to be in the spirit of what your Honor and I think, frankly, most Federal Court judges, or even most MDL judges would really want or find, and then at the end of the day when you sorted that out, maybe in six months, if we were right in whole or in part they wouldn't have to start over again.

Many of these comments — we think, obviously, all are well founded and legitimate, and at the end of the day, we hope that there may be some ways of working through them. But even if the Plaintiffs didn't agree, yes, we don't think there is a RICO claim, there are many of these other infirmities I think that can be addressed.

Again, we have had these good faith discussions, and I think our position has been to articulate them, highlight them. We are willing to have the dialogue. I will obviously wait for our friends on the Plaintiffs' side to tell us if they intend to make any of these changes or want to think more about it or

work with us on it.

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Like I said, the main issues for the Court and just for us is, we need to have targets basically just saying, essentially, that we should look at Mr. Smith and the allegation that he is from California and used the product is enough that every other Defendant should know that it doesn't apply, that is not really the way I think, with respect, it is supposed to work. Putting aside whether this is even the appropriate kind of forum or vehicle of having this Master complaint as the way Mr. Bayman pointed out, just the more practical is that there should be kind of connect the dots.

If Mr. Smith believes that he has a claim against every single Defendant, I suppose he should do that, and really articulate to the Court why that is. My guess is, they don't mean that every Plaintiff has a claim against every Defendant, but they will let us know. If that is not the case, we should avoid all we will have to do in terms of briefing, and ultimately get to what I think the Court wants, is to have briefing on the core issues.

I think the last thing I will say is, if we don't do this we are going to literally, I think, get to a point, which is probably contrary to efficiency, where we have to file massive amounts of papers, get lots of different Defendants, make it really, really hard to file coordinated -- I can't guarantee we are going to be able to file one brief in any

event, but my guess is, if we skinny these issues and people kind of knew what the targets were, that we could file probably some coordinated issues. The Plaintiffs would probably appreciate that, no doubt the Court would as well. We wouldn't have inconsistent positions.

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Then, going forward, we might actually have conversations to figure out how we could advance the litigation. For example, if we got to a point where everybody knew this Defendant was being named in this claim from these Plaintiffs, you know, we could then decide does it make sense to have initial briefing on the RICO issue, for example, or should we talk about preemption as a preliminary issue, or should we be identifying the causation issues.

I don't want to presuppose whether that was something that the Court would find attractive or all of the Defendants as a group or even the Plaintiffs, but I think we all have to think creatively once we kind of get a framed target, and unfortunately this is not one, how we could make it accessible for the Court to hopefully narrow the issues, because if we are right, then we could narrow large swaths of the case and the Plaintiffs don't have to spend a lot of time, effort, and money, nor do we, but if we are wrong, right, then we will proceed apace.

I think the last thing I will say is, what our view is, these are all very legitimate, and frankly, I am not sure

all can be cured by agreement or negotiation, but I do believe they are very substantial, they are not just procedural, they actually impact the Court's ability to manage this litigation and discovery issues and jurisdictional issues. So, our strong request would be that the Plaintiffs really take a stab at what would be a complaint that we could actually in good faith really respond to in a more targeted and appropriate fashion.

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THE COURT: Okay, thank you, Mr. Cheffo.

MR. GILBERT: Your Honor, do you have any questions before we respond?

THE COURT: I am going to let you respond.

MR. GILBERT: Thank you. I am going to kick it off, Robert Gilbert, colead counsel on behalf of the Plaintiffs. I am going to kick it off very briefly, then turn it over to Mr. Keller and Mr. Dearman who are going to address the comments substantively.

As one of the colead counsel, and in particular the one with primary responsibility for the class actions here, I want to express my great disappointment to the Court in what we have just heard from Mr. Cheffo and Mr. Bayman, and I find it necessary to say that, your Honor, as one of the four colead counsel because this needn't have been presented this way.

As the Court will recall, we originally set this date for about ten days after the consolidated and Master complaints were going to be filed, they knew they were going to be filed,

so that they would have had an opportunity to review them and to share some initial impressions with the Court and to talk about page limits and issues that would need to be briefed at the -- on August 23rd.

Consistent with that, we spent more than two months preparing, researching, architecting, drafting these class complaints, and I will say as a practitioner now of over 30 years I am extremely proud and confident in the viability of these two pleadings.

On the day that these complaints were filed I sent a note to my colleagues on the other side and I said, this is what we are filing later today, and this is how we intend to address issues of personal jurisdiction, direct filing, remand venues, and I would like you all, after you have an opportunity to look through this, to sit down with us and have a meet and confer so we can talk about these issues.

It took them ten days, until July 2nd, to find 40 lawyers from their side who could get on the Zoom with Mr. Keller, Mr. Dearman, myself, and Special Master Dodge and we listened to them tell us all the reasons why our complaints were poor, why they weren't well drafted, why they were full of deficiencies, et cetera, et cetera. At the end of that 45 minutes I said to them, so what is your proposal? Not one of the 45 lawyers on the other side could offer a proposal for us. They said, well, we'll confer and get back to you.

So, we adjourned the meeting, and two days ago I said we are still waiting for your proposal. They said, you know, we really haven't come up with a proposal. We will make our presentation to the Court at the July 9th CMC, and we will see what the Court has to say and then we will get back to you with the proposal.

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I know how important it is to you as the transferee judge here, and as the judge in any matter, the meet and confer process, but meet and confer requires a meet and confer by both sides. We have met, we heard what they said, we asked them for a specific proposal. We are the masters of our pleading and we feel very good about it.

If they don't like certain things about our pleading, if they think certain things can be cured that can avoid unnecessary briefing on August 23rd, if they want to address the proposal we made to avoid personal jurisdiction, remand venue, and direct filing issues, all they have to do is send us a proposal. And today, July 9th, almost three weeks after we filed those complaints, we have yet to receive them.

With that said, I want to turn it over to Mr. Keller and Mr. Dearman so they can address the substance of these issues, but I want you to know that we take this process very seriously, and I don't like hearing these arguments from the other side today for the first time inviting an early ruling by the Court on issues that they should be addressing with us

directly.

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THE COURT: Mr. Keller and Mr. Dearman.

MR. KELLER: I can go first. Once again, Ms. Stipes, Ashley Keller from Keller Lenkner for the Plaintiffs.

Honor. I am going to speak to the direct filing issue. We believe that direct filing the class action complaints with multiple parties as opposed to personal injury complaints is completely consistent with this Court's pretrial order.

Pretrial order 11, which prohibited multi-party direct filings, was specifically caveated by saying that the order only applies to personal injury complaints. We don't think the logic associated with personal injury complaints would apply to class action complaints. We think that it is consistent with pretrial order 30 and 31.

Perhaps more importantly, picking up on the theme that Mr. Gilbert just articulated, Mr. Gilbert sent an email to the Defendants on June 22nd, before we filed the class action complaints, and said this is what we are doing, but if you have a problem with it, if you think the direct filing is for any reason inappropriate, we have a respectful disagreement about what the pretrial orders say on that score, just tell us, because we are filing a supplement with the class action complaints telling you where each Defendant who is at least domestic and has a domestic citizenship in one of the United

States is at home, and we are going to go to your home venues for purposes of remand after these pretrial proceedings are concluded.

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So, we wanted to avoid unnecessary briefing on personal jurisdiction with respect to the domestic Defendants, and we told them in the supplement where we would go file these actions if we had to do it individually by cutting off the Defendants who aren't at home in, let's say, a state like Delaware, where a lot of Defendants are, of course, at home because they are incorporated there. We filed multiple versions of the class action complaints in those various Federal District Courts, the states of which the Defendants are at home, and then we would immediately tag them and transfer them here to the Southern District of Florida.

Just let us know, please, Defendants, by July 9th, before this case management conference, if that is your position and we can pay the extra filing fees if we have to, create some extra docket entries. It's not the most efficient way to do things, but we can do it that way.

We are not trying to deprive the Defendants of their Lexecon rights. We understand that this Court wouldn't necessarily have general personal jurisdiction over all of these Defendants. Of course, that's not necessarily compatible with Supreme Court precedent.

So, we already previewed for them the places where

these cases are going to go afterwards, hopefully avoiding or obviating a need to brief personal jurisdiction issues, and we gave them an alternative procedure that we could have followed if direct filing was, in their minds, technically improper or incompatible with this Court's PTOs, and we still haven't heard them definitively say what they would like us to do.

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We could do it tomorrow, we could just dismiss these without prejudice and go file the exact same versions of the documents with limited numbers of Defendants in each particular complaint based on where they are at home. They would immediately get tagged and they would be right back in front of you. We don't think that is practically the right way to go, but we are willing to consider that or any other proposal that the Defendants want to concretely make for us so that we can solve this direct filing issue and make them comfortable that their Lexecon rights are preserved.

Aside from that, I am not sure why we would want to burden the Court and have motion practice on the 12(e) side of the equation with respect to direct filing.

So, unless the Court has any questions with respect to that, I am happy to turn it over to my colleague, Mr. Dearman, to talk about the shotgun pleading and related issues.

THE COURT: Okay, thank you. Mr. Dearman.

MR. DEARMAN: Good afternoon, your Honor, Mark Dearman on behalf of Plaintiffs.

I would like to just take a few minutes and discuss these operative complaints, your Honor, and I am sure it is going to come as no surprise to you that we do not see these complaints as shotgun pleadings under the controlling authority. We are happy to continue discussing this issue with the Defendants. It was discussed briefly on the July 2nd meet and confer, but I would say briefly, it is not what we heard today.

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While it seems -- it seems to me that the Defendants are looking for this perfect complaint, and while the Plaintiffs have strived to deliver a perfect complaint, your Honor, you yourself in ECS versus Martin County said that's not what is necessary, it just needs to be a sufficient complaint, perfection isn't required.

A lot went into the overall strategy in this complaint and it seems like a lot of Defendants' arguments, and maybe the reason why we are hearing them for the first time today, is just because they are premature. It sounds like they want to argue class certification today. It sounds like, if they don't want to argue class certification today, that they are saying to the Plaintiffs, well, you should have filed 93 separate class actions, and we don't see it that way.

As I said, the overall strategy was well thought out. The cumulative group of lawyers who you selected and their teams got together and spent a lot of time to come up with

these complaints in what we thought was a thoughtful manner, a practical manner, and a sufficient manner, and a way to get to class certification; decisions such as which Plaintiffs to include from all over the country, decisions to include which Defendants. And you have heard and you know that these products have been on the market for a long time, there are a lot of Defendants.

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The decision to tell the story that we have told and the way that we have told it, to plead the classes the way we have pled the classes, to include the causes of action we have included, and to plead them the way we did, it is not a shotgun pleading.

Your Honor, we have nationwide classes, we have statewide classes. We have nationwide claims, we have statewide claims. And these statewide claims wasn't just the shotgun approach, let's plead every state claim. In fact, for example, if you look at negligence and you look at battery, we particularly selected the states where those claims are recognized to make it easier for the Court to rule on any motions and to provide the Defendants notice of what they are being sued for.

What I am hearing from the Defendants is, too many, too many Plaintiffs, too many Defendants, too many claims, but that is not the yardstick with which you measure whether this pleading is a shotgun pleading.

At the end of the day, the complaint clearly provides the Defendants more than adequate notice of discrete claims, yes, a lot of discrete claims against them, and the grounds that support those claims. It puts them on notice.

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If your Honor would like, I will take a few minutes and discuss the architecture of these complaints. I am sure you have had an opportunity to read them, but the Defendants said this is a 1300 plus page complaint. Your Honor, I would suggest if you look at the Juul complaint, it is also about 1300 pages.

THE COURT: I don't think so. I have looked at the Juul complaint, it is not that long, if my recollection --

MR. DEARMAN: Your Honor, I don't mean to cut you off, but that's interesting because I had the same feeling when I read that complaint. If you take a look at the complaint, where it talks about the Plaintiffs in the litigation, there's about 400 of them, instead of including those 400 Plaintiffs in the complaint, what they did was they included an appendix to the complaint which is almost 420 pages, that's my understanding. So, when you look at the 600 plus pages of the complaint and you add the 400 plus pages of the appendix you get to that 1100 or 1200 number. I'm not great at math. I think it's important to point that out.

Although we didn't go about this effort to determine how long the complaint was, we went about it to make sure that

we put the Defendants on notice, and that we would make it as easy as we could on the Court.

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While the Defendants are saying, well, we don't know what we are being sued for, they do know what they are being sued for. I actually had somebody in my office, I said here is the complaint, do me a favor and with the complaint put together a chart and let me know the claims that are included and which Defendants are being named with regard to those claims. They put that together without having any outside knowledge.

We clearly describe the Defendants that are being sued for specific claims. We include — as far as the Plaintiffs are concerned, because we are hearing too many Plaintiffs now, I guess we could have filed these complaints with five Plaintiffs, but then we would have heard, well, you didn't name enough Plaintiffs, you have standing issues, you have adequacy issues. It wouldn't have been enough for five, it's too many for 230, but we feel like we have really covered the waterfront.

I could go over a couple of different paragraphs in the complaint. They picked the D.C. Plaintiff. There are Plaintiffs from 40 plus states where we include what they took, when they took it, why they took it, where they purchased it. We provided the what, when, where, and why. We clearly meet the Rule 8 and Rule 10 pleading requirements.

So, you know, I am not really sure, without having more information from them, as to what they are suggesting that we do. I looked at the controlling law on shotgun pleadings. We don't incorporate other counts. We incorporate the story that we're being told, but that story is background, that story applies to these Defendants.

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Mr. Agneshwar said that -- I don't mean to pick on him, but I think he said a 2010 study doesn't apply to his client. Yes, it does apply to his client. His client has the basis to know about that study and to understand that and has better information than the Plaintiffs that we represent. I could go on.

THE COURT: Let me -- we definitely have hit a hot topic here, and I know that there is probably much more to be said, but in the interest of wanting to get through the agenda in short order, we want to cover some topics on discovery, and then I think it probably would be wise to conclude. I don't want to overtax everyone, including Ms. Stipes.

Here I am just going to give you some general observations. We may very well want to have another opportunity to speak that is including the Court in the appropriate manner on the class complaint -- complaints, but first, I think the parties need to meet.

So, I don't want this issue to be, you know, the one that sort of breaks the notion of goodwill between the parties.

There seems to be some concern that maybe not all of the points were raised by the Defense for the Plaintiff beforehand.

I just want to make it clear that no one should feel that you are being disadvantaged by the Court hearing things at this stage. We are not at motion practice, I am not taking anything that is being said as sort of argument, advocacy for the purposes of substantive legal issues.

I know that, you know, some of the areas have gotten into some of the legal buckets, if you will, but, you know, I don't want anyone's feathers to be ruffled over this. I know, Mr. Gilbert, you were expressing some dismay. I would like to just encourage everyone to take a step back. You have accomplished so much. This is a big one, this is a big complaint, it's over 1300 pages, and from the Plaintiffs' standpoint, I can understand why you may be proud and certainly clearly devoted a lot of time and effort to it, but from the Defense standpoint, there are issues that they have concerns with.

I suppose you can only meet and confer in great detail about so much before a status conference, so I am going to just assume that the process has begun, but just didn't have an opportunity to come to full fruition and completion prior to today, rather than any one party trying to hold back information to only unduly surprise, unfairly surprise another side. That is not how you all have acted, and I don't think it

is anyone's intention to do that and the Court doesn't see it that way.

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So, first and foremost, I don't want this or any other issue to set the dynamic back. That would be unfortunate.

Now, that being said, I can understand why something like this document, this pleading would engender a lot of feelings for the reasons I have just outlined, the hard work on the one hand and the reaction on the other.

I think there is work to be done between the parties to talk about this. I have not evaluated it with the level of detail and don't know it with the level of knowledge that you all speak, honestly. The nuances of direct filing, the personal jurisdiction, the remand issues, those are perhaps for another day, or maybe some of those issues can be resolved before they come before the Court for a ruling.

What I do know is that -- and it is not just about the length, but it is a long complaint, it is over 1300 pages. It has over 300 causes of action, it has two national classes, it has 52 state classes. Some causes of action are common to all state classes such as negligence and battery. All of the other state causes of action are specific to each state class.

I did note the structure is different than in Juul and Valsartan. I saw that there were different structures to how those complaints were drafted. I don't know how well they have worked or not worked. I don't know whether Plaintiffs' counsel

has any insight into how well they worked or not worked or whether there was any intention to model or not model this complaint after any of those, but I have reviewed those other complaints.

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I am struck with a workability concern, to be honest.

I am not really going to go any further than that because I am not here to opine on legal issues and the merits of any claims that are made. I am not in a position to do it nor would it be appropriate for me to do it.

What I am concerned about is the workability of the document. What do I mean by that? I mean the workability of the document, the pleading, from the standpoint of it being responded to by the Defendants, and the workability for the Court to handle it.

What kind of motions might this generate? How many motions might this generate? Is the Court to handle all of those motions at the same time, or how many issues, I should say, you know, if there is going to be consolidated motions, how many issues? Should all of those issues be brought before the Court at the same time? Should there be sequencing of some of these issues? Should all of the causes of action go forward at the same time? Is there any kind of clear delineation between the national class and the state classes?

I am just sharing with you some of the things that went through my head as I read it, again, not evaluatively in

terms of whether there's merit or not merit or whether certain Defendants should have been named or not named, but just kind of from the workability of the document. I have to be honest, it gave — and I am talking specifically not about the third payor, but the class — nationwide class and state class complaint, 1300-page complaint.

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I would ask, I would request, I would require that the parties go back to the drawing board to pick up from the discussions that began, but perhaps did not get far enough before this conference, and that's fine. The conference had many things on the agenda, this is not all about the class complaint, and sometimes putting conferences at certain times is good because it brings issues to the surface that might otherwise have been buried for another couple of weeks or a few weeks. So, I look at this as a good thing.

I don't want anyone to feel set back by what has come out today. I think that this kind of airing of concerns is productive, particularly when we are talking about a substantial complaint that implicates all of the Defendants in so many causes of action with different classes.

I just started to think, what would this look like if this even went to trial? How many causes of action would be put before a jury?

I would need to better understand the workability of this document, of this pleading to get comfortable with it.

And so -- but before I need to get comfortable with it, I would feel better if the parties were on the same page in terms of at least understanding why it is put together the way it is put together, whether there is a different way structurally, let's say. I have no doubt that the same vetting and exchange of information that we talked about in the context of the registry, in the context of the PI complaint would be equally applicable here. So, in terms of claims against certain Defendants, I would hope and expect that that vetting process would play its way right into this complaint.

Structurally, I would ask that there be some discussion of how this can be a workable document for the Defendants to respond to and for the Court to manage motion practice on in a way that keeps everything else going, and also class certification motions.

I had a question about how many class certification motions would a complaint like this generate. Maybe someone could answer just that question.

Is it contemplated it would be one or is it motions for both national classes as well as 52 state classes?

MR. DEARMAN: Your Honor, if I may.

THE COURT: Yes.

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MR. DEARMAN: I think we are seeing it as one, but that shouldn't preclude the fact that there might be more than one. I know that is not maybe completely responsive to you,

but we would plan on one, but that doesn't mean that as things shake out and as discovery comes in and as we get further to define the classes, we wouldn't want to make it more manageable.

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THE COURT: For the record, that was Mr. Dearman.

I think that is all that I would like to say. I think it is incumbent upon the parties to sit down and hash this one through.

I always believe that -- again, just even on the shotgun aspect of it, if we want to wait until the right date of Motions to Dismiss, which I think is somewhere in October for the Court to -- October -- November 21st actually, the replies. Do we really want to wait until November 21st for the Court to come back and say yes as to certain claims, certain Defendants, certain parties, shotgun pleading, go back to the drawing board and amend, or do we want to catch these issues on the front end and have amendments, if agreeable voluntarily, without a Court ruling?

Which again is consistent with how Judge Reinhart and I often work, where a complaint may lend itself to, let's say, a 12(b)(6) kind of motion. So, we catch it on the front end, but we are not extending the period of briefing and particularly here where the briefing is so much longer than in a non MDL case. I just don't think you want to wait until November 21st to find out the Court's view on whether this

needs to be repled in whole or in part to address issues that are brought up by the Defense based on, let's say, a shotgun pleading argument.

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Again, that is a hypothetical general statement. It's not to be construed as the Court has construed the complaint as a shotgun pleading or that there are valid legal claims as to direct filing or personal jurisdiction, but I do want to signal to you that I have concerns about the workability of this pleading.

If for no other reason, I would ask that that be addressed and to think through creatively on how the Plaintiffs can accomplish what they need to and want to accomplish. There was a negotiated deal to have the class case going parallel with the PI. We went through that, so I am committed to that, but if you want me to do that — you know I am one person with just a magnanimous staff, but we are a small staff, you have to think about how am I going to do that with that kind of complaint pled the way it is pled.

How is the Court going to manage it from motions to certifications to any potential bellwether if that is contemplated with the class complaint? Maybe it is not, so I don't want to speak out of turn.

If for no other reason, I ask you to take a close look at it, how you can accomplish what you, the Plaintiffs, want to accomplish, and I want to credit you for the hard work. I have

no doubt this was a difficult document to put together and took a lot of time and thought. This is a very intelligent, bright, and accomplished Plaintiff's team. I recognize and appreciate what the Defense are saying and I don't want the Plaintiffs to have a knee jerk reaction because of those articulated concerns.

Maybe you are not completely content with how it came out today and that it did not come out fully in advance, but let's move on from that. The bottom line is, it is now out and how do we address it and how do we move forward productively so the class Plaintiffs can move forward and PI Plaintiffs can move forward and the Court can do its job in managing this case.

I think that is all I really want to say about the class complaint if that is okay, and let's just move on to the status on discovery --

MR. GILBERT: May I ask a quick question, Judge, before we move on?

THE COURT: Yes.

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MR. GILBERT: Given the August 23rd deadline -- and we all appreciate your comments, and we take them in the spirit they were conveyed. Thank you. Bobby Gilbert on behalf of colead counsel for Plaintiffs. Excuse me.

Given the August 23rd date, if the parties, following some additional meet and confers, wanted to get together with

1 the Court solely to discuss the class complaints issue, is that 2 something the Court would be willing to consider? 3 THE COURT: Yes, absolutely. It may mean that that 4 August 23rd date is not the date for this complaint. That may be -- or because of that date, certain things need to be done 5 6 to meet that date, but absolutely. 7 MR. GILBERT: Thank you. 8 THE COURT: Okay. I am going to try to wrap this up 9 by 1:30. 10 With status of discovery, I am going to call upon for 11 the brands -- is it Paige Sharp and Mr. McGlamry and Ms. Finken? 12 13 MR. McGLAMRY: Good afternoon, your Honor. THE COURT: Good afternoon. What can you tell me 14 15 about an update on brand discovery? MR. McGLAMRY: Your Honor, let me first say to start 16 17 with, with Ms. Sharp on the phone, that we get along a whole 18 lot better than that class crowd does. 19 THE COURT: They just want to make you look good. 20 MR. McGLAMRY: I know that, and I appreciate that. 21 Plus, with Ms. Sharp, I don't have to repeat Pulaski and 22 Petrosinelli and get tongue tied, but I will say, your Honor, real quickly -- and I thought about this to say more, but given 23 24 our time I am not, but for those people particularly that

haven't been involved in this yet or just gotten involved,

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there is an enormous amount of work that has gone into everything in this case, as you know, but with regard to discovery particularly.

As I have looked back at sort of when some of us were initially appointed until now, it has been about a hundred days, and as you mentioned earlier, we have 33 PTOs that we have ultimately either negotiated in part or have been involved in.

We have -- you know, we have already had document production, we have already done what typically takes a long time in any other litigation, in part, I believe because of the COVID pandemic and the fact that most of us are in our basement or our home office all day long.

What I want to say on behalf of -- I think this is for Ms. Sharp and our side as well, we spent a lot of time on discovery and PTO 15, which came out I think the 1st of April, required us to get together and meet and confer and talk about initial production. That is the section I am going to talk about. Ms. Finken is going to talk about sort of the next step beyond the initial production.

I will say that we worked very diligently together both as a group of the brands, as well as individually breaking out with them to come up with sort of a path forward with the initial production, and we talked about what could be produced in the near term and then a timeline for what could be produced

thereafter based upon a set of requests that we had provided to the brands. I say all that in part to talk about the brands, but ultimately, that is essentially what we did with the generics, so that will shortcut some of that discussion next.

As a result of that, your Honor, and having worked out the ESI and confidentiality, preservation, and privilege orders so that documents can start to be produced, we have started getting in document production of the initial production from the four brands.

I want to say that somewhere over 2 million pages of documents have been produced. Most of that by GSK, but each of the other three have also had productions and we expect, for example, an additional one from VI tomorrow.

So, that process has worked, we are getting the information that we were talking with to them about for the initial production, and I think that has enured to both sides' benefit of being able to do it that way such that on the one hand, from the Defense side, because of COVID and so forth, they have sort of defined things to look at as a first stage, and for us, because we needed to get started anyway and the most appropriate, probably, starting point is the regulatory and testing materials anyway.

I would just say that, obviously, we are working through the finalization of that initial production, but I think it has been a very positive and advantageous process.

Thank you, your Honor.

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THE COURT: Excellent. Thank you.

MS. FINKEN: Your Honor, Tracy Finken from Anapol Weiss on behalf of the Plaintiffs again.

Just to add to that, I am going to go into a little bit of the specifics that we have been meeting and conferring with regard to the discovery with the four brand manufacturer Defendants in particular.

We served them on June 16th with formal interrogatories and requests for production of documents. Since then, Ms. Sharp has asked for a 60-day extension until September 15th to respond on behalf of all four brand manufacturer Defendants. We have responded to Ms. Sharp that we are agreeable to work with them on the timing of the response as long as the response is planned to be substantive and not blanket objections to the interrogatories and requests for production.

We have a meet and confer scheduled on that for, I believe, Monday or Tuesday of next week, so we are working through that process.

We have also been in the process of meeting and conferring with each brand manufacturer Defendant for them to identify noncustodial sources of information, legacy as well as current databases and share files, and things of that nature, so that we know where the categories of information are

contained that we are seeking, and to what extent that those noncustodial sources of information are Zantac specific.

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In that regard, when it is a Zantac specific noncustodial source of information or file, we have an agreement with at least Pfizer to produce those specific files and documents, obviously subject to privilege review, but in their entirety without the use of search terms.

We're also in the process from each Defendant getting — for them to identify the noncustodial sources of information that are shared with other products, they aren't necessarily Zantac specific sources of information such that we would need to run search terms across those databases or share files, or wherever that information is located, as well as identifying search terms that we would be using in terms of custodial file production and searches of custodial files.

That initial list of search terms has been exchanged with Pfizer, and they are in the process of test running some of those search terms, and we are going to have a meet and confer next week for them to provide us with basically head count reports to determine how or why or if we would need to modify those search terms at all. That is something that we have a meet and confer scheduled for next week.

We are in the process of modifying the search terms a little bit for the other brand manufacturer Defendants that would be specific to those Defendants, supplementing it just

slightly with information that we have received through their document productions to date.

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For example, if there was a specific product name or an identifier or a clinical trial, or something like that, that we would need to add, we are i the process of doing that and we should have that initial proposed list to the rest of the brand manufacturers shortly.

We are hopeful that we will be able to engage in the same process with the other three brand manufacturer Defendants that we have engaged with Pfizer and we will hopefully have some meet and confers scheduled in the short term to continue that process.

The other part of the formal discovery that we have served has been 30(b)(6) deposition notices for all of the brand manufacturer Defendants, mainly on foundational topics such as regulatory, pharmacal vigilance, clinical trials, things of that nature, and hopefully we will -- we have not heard from the brand manufacturers on those 30(b)(6) notices at this point, but we are willing to work with them on the dates and timing for those 30(b)(6) depositions, as well as doing them through a Zoom forum or format if we cannot be live, which we have done in other cases and we are certainly willing to do.

In addition to that, Boehringer Ingelheim has identified custodians that they have been able to identify as having relevant information for us. We have noticed

depositions for those custodians at this point. I know that the other brand manufacturer Defendants are in the process of identifying potential custodians for us to start the process of taking depositions and hopefully we will receive those soon.

So, we are moving forward, working with Defendants trying to get the discovery done in an expedited basis and get the information we need so we can move the case along.

With that, I will turn it over to Ms. Sharp if she has anything to add.

THE COURT: Thank you so much.

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MS. SHARP: Thank you, your Honor, and good afternoon.

This is Paige Sharp from Arnold and Porter on behalf of the

Sanofi Defendants. It is nice to see everyone again today.

I will try to keep this brief because I know your Honor is trying to move things along. I do appreciate Mr. McGlamry and Ms. Finken providing that overview and agree that the parties have primarily been using a collaborative meet and confer process to advance the discovery effort.

As Mr. McGlamry said, each brand has now made an initial production, but of course the scope and substance have differed and productions will continue to differ among the Defendants because each had the product at different points in time, including at different points in the life cycle of the product.

Having said that, these initial productions for the

Defendants primarily focused on regulatory files such as investigational new drug application materials for Zantac, new drug application materials correspondence with FDA. The types of documents produced included adverse event information, annual reports, NDMA testing results, and Sanofi in particular produced the Zantac recall package that it submitted to FDA.

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As Tracy described, the parties are also working on next step for document production. With respect to those, we expect them to include additional regulatory file materials, some manufacturing and quality agreements related to Zantac, organizational charts and standard operating procedures for various functions of the different companies, and we are continuing to discuss with the Plaintiffs, as Ms. Finken said, noncustodial and custodial sources for document collection and production.

I did want to briefly address the formal discovery requests that were served on the Defendants as well as the 30(b)(6) notices. We did -- in addition to requesting an extension of time to respond to those formal requests, I had a meet and confer with Ms. Finken and Mr. McGlamry to discuss those, and the fact that we are primarily working through this informal meet and confer process and that we view the formal discovery requests as premature for that reason, because we are still in the relatively early stages of collecting information and materials that will be responsive to those requests. My

understanding is that in particular, the Plaintiffs agreed that the requests for production will be responded to over the course of these ongoing informal discovery negotiations in which the parties are agreeing to the scope and substance of document production.

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And with respect to the interrogatories, they had wanted a firm date for our response to those, and we have a meet and confer set for Friday to discuss a deadline for those responses.

I believe that that is where things stand from the branded Defendants' perspective.

THE COURT: Okay. Thank you. It sounds like everything is going very well and that the parties have worked out a process that is amenable to where you are with the brands.

Is there anything that the Court can do to assist or are you fine without any Court involvement at this point?

MS. SHARP: Again, this is Paige Sharp. On behalf of the branded Defendants, I think we are working together well and advancing discussions and the production, so I don't think there is anything for the Court to address at this point, but we certainly appreciate that, your Honor.

MR. McGLAMRY: Yes, your Honor, on behalf of the Plaintiffs, I think we are working well together. My only concern might be the comment that Ms. Sharp said that they are

in the early stages, in the sense that we have a pretty tight time line, and early stage needs to get to the end stage quicker than in most litigations, like everything else in this case.

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But otherwise, I totally agree with her, and as you know, as far as we're concerned, she is actually lead counsel of the four colead Defense counsel, so we have a very good relationship with her and are working with her and others amongst the brands to get this done.

THE COURT: Excellent. Wonderful. Thank you for leading off the status of discovery report with such an excellent report. It is a good model to follow and I look forward to hearing now updates from the others, but thank you so much for your hard work. I know it doesn't come without investment of time and hard work, so I very much appreciate that.

MR. McGLAMRY: Thank you, your Honor.

MS. FINKEN: Thank you, your Honor.

THE COURT: I think we are now turning to discovery of the named class representatives. Is it Mr. Gilbert and Mr. Bayman on that?

MR. GILBERT: Yes, your Honor.

MR. BAYMAN: Yes, you Honor.

THE COURT: You have a tough act to follow.

MR. BAYMAN: Thank you, your Honor, Andy Bayman again

on behalf of Boehringer Ingelheim and one of the Defense coleads.

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Good news on this front also, your Honor. We have had some very productive discussions, Mr. Cheffo and I, with Mr. Gilbert about some informal discovery to the class representatives that could be produced early. We have met and conferred and have identified certain categories of documents that Mr. Gilbert and the Plaintiffs will be producing from the consumer economic loss only Plaintiffs, from the consumer Plaintiffs seeking medical monitoring, and from the third party payors.

We have worked out an acceptable list for that early discovery before we serve formal written discovery, which will be served soon. We have set a target date for the Plaintiffs to respond to that of 60 days, while at the same time Mr. Gilbert indicating he would be producing some of the information on a rolling basis, and also Mr. Gilbert asking if more time were needed on certain things, we said we would be amenable to a reasonable extension of that.

So, I think we are moving forward with some of the type of informal discovery that you see going on on the personal injury side.

THE COURT: Excellent. Thank you.

MR. GILBERT: Judge, I agree with everything Mr.

Bayman reported. I will say one thing that he is aware of. We

may be calling upon the Court, we are not sure yet, with regard to the production of information from those Plaintiffs seeking medical monitoring.

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We are contemplating the possibility that it may be more efficient and better for both sides to seek some sort of provision that relates to PTO 15 for document and medical record retrieval through a third-party vendor, an independent third-party vendor. So, we are early in those conversations, and I don't want the Court to be surprised if, following some further discussions with Mr. Bayman and Mr. Cheffo and our team and Special Master Dodge, if we come to the Court and ask for a supplement to PTO 15 that might encompass this aspect of it.

THE COURT: Okay. I appreciate that and I will look for that.

I wanted to just pick up on a theme that has been mentioned, and I know Judge Reinhart feels very strongly about it as well, which is reference to rolling production. I think that that is excellent and it doesn't seem to really make sense to hold on to everything and then wait until the last minute and say, we don't have it and here is why, or dump it all on at the last minute.

So, I think in the spirit of continuing to communicate and work together, rolling production is something the Court, and particularly Judge Reinhart who deals with a lot of discovery issues, has found in his experience, as I'm sure

counsel have, to be very effective as a way to proceed with discovery.

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So, I just wanted to pick up on that and thank you also for that excellent report, and I appreciate it very much.

MR. BAYMAN: Thank you, your Honor. I'm sorry for the technical difficulties with my camera earlier.

THE COURT: No, no issues at all, no worry.

All right. If that is all on the named class rep discovery, we have for the generics Mr. Barnes, as I understand it, and Mr. McGlamry and Ms. Finken.

And I know that -- I will preface any remarks that you want to make with, you know, I am aware that you are working, maybe not having finalized the proposed pretrial order that you intend to submit to the Court regarding how the parties will work together, that is the generic Defendants with the Plaintiffs.

I thought that it was a very good arrangement. Maybe you are looking at just some of the particular language right now. It seemed to capture the notion that maybe certain Defendants have certain documents more readily available than others. There was an identifiable group of ten categories for the discovery agreement and, you know, as the Court had said awhile back, you know, it is not going to stay discovery.

So, as a way to move forward, I recognize that maybe there are individual issues and differences with different

Defendants, I felt that your core discovery agreement and the order that you are seeking to have the Court enter once it is finalized seemed to reflect a really fair and reasonable process.

I want to acknowledge the hard work that has been put forth by the generic liaisons — I know we have Mr. Barnes on the screen, Mr. Yoo as well, although he is not on the screen — because you do have to balance the interests of all of the generic Defendants, and there are many of them, and individual situations which may be very different from one another, and balance that with the larger interest of engaging in a collaborative and coordinated process in approaching discovery.

So, with that lens, I looked at that proposed order and felt that you had really done a very, very good job, and I hope that the other generic Defendants who are new to the case and are trying to get up to speed understand your leadership role, and actually to that end, the last PTO that the Court entered, which I made reference to earlier -- I know this is off topic with the discovery, but it does fit into my discussion about role of generic liaison counsel -- PTO 33 highlighting the importance of being able to solicit the views of the many generics, but at the end of the day, taking those views into account, but then you come to the table, you are working with the other Defendants, you are working with the

Plaintiffs in arriving at an outcome that is balanced, fair and reasonable.

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So, I just wanted to take a moment to applaud the parties' efforts in that regard and look forward to receiving ultimately the final version of the PTO that you would like the Court to enter.

So, with that, let me turn it over to counsel for any comments that you have as to where you stand.

MR. McGLAMRY: Thank you, your Honor. If you don't mind, I will start. Also, I think you made a very good point about particularly the newer generics trying to get up to speed, and I will say that, except for maybe Mr. Bayman, I may be the oldest lawyer in the crowd. I'm teasing, I am much older than Andy. But this has been the most transparent and collaborative sort of meaningful case management I have ever been involved in.

On the discovery side, I don't think people from the outside -- what I mean by that are newer counsel or generic clients coming into this -- can really appreciate how the sausage has been made in this process, and how that started between your Honor and Judge Reinhart and Special Master Dodge, and the coleads and so forth working through all of this all the way then to the generics.

There has been a lot of thought put into this, and from our perspective, how we looked at this as it relates to

the generics. We started with the brands because, obviously, we had all of the brands.

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There were only, as I recall, six original generics involved among -- I don't know the total number of potential generics that is out there, but obviously multiples of the brands. We worked through with the brands the initial production context, and then we went next to the generics and talked with Mr. Yoo and Mr. Barnes, and we had a conversation with all of the six generics, much like we started with all of the brands, and talked about, and you mentioned it a moment ago, your Honor, the list of ten items that we had put together as core discovery requests, sort of noncustodial elements of requests.

So, we went to them and said, look, we have PTO 16 which requires us to do this initial production context, both in the near term and a timeline for additional production, and we would like to offer a little bit more in terms of sort of an additional piece to this, is that we think that it would make sense, not only because we wanted to focus initially on the brands in terms of the full discovery, which you heard

Ms. Finken talk about in terms of the search terms and the full sets of formal discovery, but instead what we had talked to the generics as a group and -- was let's do this initial stuff first and that will give us all time to get involved.

You guys are just coming in for the most part to this

litigation and we are going to have others, because clearly there are going to be more generics coming in. So, I thought we did a pretty good job of working through an agreement with the six original generics.

We had that group call, then we broke out individually, Ms. Finken and I, with each of the sets of counsel for each of the six generics and talked to them about their particular circumstances in terms of trying to find out some of the information that we were talking about earlier, about when they manufactured, who their API manufacturers were, and timeframes and so forth, and kind of sorting it out. We talked about the production and how they could do that and where their companies were situated.

We ultimately came to an agreement, had a deal sort of in an informal way, and hold off on custodial discovery until we could work through that, and that we reached an agreement on that, which we believe and hope is the foundation for a PTO that your Honor will hopefully enter into shortly. We think it is fair.

The way we kind of look at this that may have gotten lost in the shuffle here is, we could have served all the generics with full discovery in the beginning, we had every right to do that on June 15th, but we thought that it made more sense, it was more reasonable, it was more in line with sort of the way the parties had all been dealing with each other and

with the Court in this, and we would rather do it that way than, in many instances, the old fashioned way, because there has been nothing about this case that has been the old fashioned way, primarily because of COVID and how we have had to sort of operate since then.

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So, we feel like that is a considerable concession on our part, but that we are willing to do that because it makes sense in the timing of all this. I think that is true with Mr. Barnes and Mr. Yoo, and I am hopeful that that will carry forward with the remaining generics, as well as, as I mentioned, if the Court could enter the PTO with those coming in along after us.

With that said, I think we are making progress, as we typically do with this crowd, and I appreciate what Mr. Barnes and Mr. Yoo have brought to the table.

THE COURT: Thank you, Mr. McGlamry.

MR. BARNES: Good afternoon, your Honor, this is Rick Barnes and I am one of the liaison counsel. Thank you for your remarks.

I don't have a lot to add to what Mr. McGlamry said.

I would say that Mr. Yoo and I have communicated to our generic manufacturer colleagues that one of the benefits that we think we have offered our group is to defer the production of noncustodial files at the outset of the litigation for a significant period of time.

The deferment of formal discovery I think will also benefit the generic manufacturers and the Plaintiffs, but also unburden the Court with the inevitable objections and the like that would almost certainly arise from formal discovery.

I agree with what Mr. McGlamry said and appreciate his hard work, but I'd also like to mention the special master, and she has been tireless in working with us and with the new generic Defendants in order to explain the process not only as to discovery, but as to all the other aspects of this litigation.

The hour is late, but I think Mr. McGlamry has accurately summarized the status of the generic discovery.

THE COURT: I appreciate that.

Was there anything you wanted to add, Ms. Finken?

MS. FINKEN: Nope, I think that they have covered the crux of the agreement and what we have been discussing so far. I am just here to keep them both honest today.

MR. McGLAMRY: I was going to say that, your Honor. That is her role, to make sure we did it right.

THE COURT: You did good. Well, great. I think two really critical issues, among others, have been highlighted for the benefit of all newcomers, and particularly the generic Defendants. We started off this morning, it seems like a long time ago now, I am sure everybody is a little hungry and tired, but, you know, talking about the registry and the benefit of

the registry, and at the end of the day, it is every

Defendant's option whether to agree to the registry and tolling

or not, but hopefully most, if not all, were persuaded of its

benefits.

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Similarly, I think the parties have done a terrific job with leadership by Plaintiff and Mr. Barnes and Mr. Yoo, whom I have given much trust and authority, again, even as recently as this morning with the additional PTO, that there is an opportunity to engage in an informal discovery process through this core agreement, the core discovery agreement that holds off to some extent on formal discovery with the idea of producing, narrowing, winnowing, refining, clarifying.

So, a little bit of patience and some work to exchange these documents I think will ultimately behoove everyone. So, I hope the generic Defendants feel they have learned much about these issues and will strongly consider it. And I know counsel is always available to answer questions for them if they are considering whether to opt in or not to this core discovery agreement.

With that, I thank you, and I think we are concluding our discovery update with the retailers, Ms. Johnston and Ms. Finken and Mr. Pulaski, if I have that right.

Good afternoon, Ms. Johnston. Who would like to start off with the retailer update?

MR. PULASKI: I will jump in. This is Adam Pulaski on

behalf of coleads for the Plaintiffs and Plaintiffs leadership.

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I will echo everything that Mr. McGlamry just said as it related to the generics, also as it relates to the retailers. I know there are a number of retail Defendants that are just now making appearances or who have not made an appearance yet, but may be on this call. We have met and conferred with Ms. Johnston on several occasions as it relates to discovery matters.

We have made a proposal and had lengthy discussions, including Special Master Dodge who has participated on the calls as well, and Mr. Atleff (phon) who represents Wal-Mart, but for the most part, Ms. Johnston has been speaking on behalf of most of the retailers that have been named so far in the litigation and others that may be named in the future.

We are working towards an agreement as it relates to a minimal amount of initial discovery and disclosures for the retailer Defendants. We are not quite there yet, but I know Ms. Johnston has not had all of the time in the world because, like we discussed, some of the parties just came into the mix, and she has been working diligently on that.

I am hopeful that as it relates to coming to an agreement that we can enter into a PTO, that we will get there. We have been working on this daily, even as early as this morning right before the conference. We have more discussions to come after the conference and tomorrow and the next day, and

I am hopeful -- you know, she -- Ms. Johnston has some very strong opinions as to certain issues that we are agreeable with, and some that we have to make some minor modifications and some changes that we can discuss later.

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But again, I think we are well on our way -- and I will not hold the Court up any longer, this has been a long day, but we are well on our way to getting where we need to be.

THE COURT: Thank you, Mr. Pulaski. Ms. Johnston.

MS. JOHNSTON: Yes, thank you, your Honor, good afternoon. For the Court Reporter, this is Sarah Johnston for the retailer Defendants.

Yes, I think that everything that Mr. Pulaski has said is accurate. We have had a number of discussions about getting to a streamlined set of discovery that hopefully can be incorporated into a PTO similar to what the generic Defendants are working on.

I think that we are in agreement as to the general topics of discovery from the conceptual standpoint. There are just a few issues that we need to iron out that I think are retailer specific, but as Mr. Pulaski said, we are working through those and will continue to work through them, and I think that we are very close to getting an agreement that we can put before the Court.

THE COURT: Wonderful, I am pleased to hear that.

There were just a couple questions I had. I heard

much today about product ID issues and how critical that is to getting past some of the early vetting issues. I understand that retailers would have key documents like NDC codes and pharmacy records, customer purchase records that are key to the product ID issues that have been discussed.

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Is there a plan for turning over that information since this has been discussed for some time now?

MS. JOHNSTON: There is, your Honor, and I think that there are going to be two issues that we will need to figure out an agreement to overcome. The first is the volume of anticipated Census Plus forms and how quickly a particular retailer can pull and collect and receive prescription records and loyalty card records that have PPI and will need some review before they can go.

I think the proposed solution is that those will go in a rolling production format as was discussed by the brand name Defendants.

The second issue is the fact that we have got so many retailer Defendants who are new to the case who have just appeared in the litigation or have yet to appear and they are going to have certain IT infrastructure requirements that are going to need individual meet and confers with Plaintiffs in order to be able to access that data and pull it in a reasonably efficient form.

Yes, I think that the plan is to tie that to when we

start to see the first tranche of Census Plus forms coming in 1 2 and to reach an agreement on a period of time after those forms come in that we can start to roll those documents out. 3 4 THE COURT: Is this envisioned to be part of the 5 proposed order that you are alluding to that I would hope the 6 retailers and the Plaintiffs would enter into, much like the 7 generics have with their core discovery agreement? Is that where we would likely see product ID and NDC codes and things 8 9 of that nature, as part of that proposed order? MS. JOHNSTON: Yes, your Honor, it would be, and 10 Ms. Finken sent us a draft of the order with --11 12 THE COURT: I think she just froze. 1.3 MS. JOHNSTON: I am sorry. 14 THE COURT: You froze so we missed the last part. 15 said, you think Ms. Finken --16 MS. JOHNSTON: I'm sorry. Yes, Ms. Finken sent a 17 draft of the order, as I understand, it is similar to the one 18 the generics are working through, a night or two ago, and -- am I frozen? 19 THE COURT: You are going in and out. I am so worried 20 21 about jinxing a good thing. 22 MS. JOHNSTON: Of course, perfect all day, and just 23 now. 2.4 THE COURT: Right. So, core discovery agreement, 25 proposed order similar to generics. I don't want the retailers

falling behind, so hopefully something will come my way -today is Thursday -- if not by tomorrow, maybe by Monday. Does
that sound realistic? I know the generics probably have
something waiting in my in box somewhere as they were just
about signing off on it.

Are we kind of that close with the retailers?

MR. PULASKI: She is very still or she may be frozen.

We are close, we have some issues to resolve. I think the reasonableness of a rolling production of prescription records and loyalty program records is easy. I know that there are some IT issues as it relates to different retailers because there truly is no uniformity amongst the retailers as to how they control their loyalty programs, and Ms. Johnston has educated us on that aspect of it.

So, we do need to probably meet and confer with them individually just to get some data so that we can actually request the information properly, and a few other items that are more significant that we will talk about today with Ms. Johnston, but I don't see a reason why we can't finish this up by tomorrow.

THE COURT: Okay.

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MS. FINKEN: Your Honor, Tracy Finken for Plaintiffs.

Just to add to that, we do have a draft going, it does mirror the generics draft substantially. It is something that Ms. Johnston said she would be looking at, talking to her

clients about, and she will be getting back to us shortly on that with edits or modifications to it.

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We have also discussed the need for the registry claimant, loyalty rewards card, and prescription information to be on a rolling basis because the registry will be changing as we move forward. While this initial tranche will be large with the August deadline, there will be new claimants registering and being added to that on a rolling basis as we move forward through the litigation.

So, just by necessity, with the way that the registry is set up, the production of those documents will have to be rolling and that is something that we have discussed with Ms. Johnston on prior meet and confers.

THE COURT: Okay. I want to recognize, Ms. Johnston, the difficulty of your job, as I have with the generic liaison, given how many retailers are in the case, but as with them, I entrust you with the ability to, obviously, communicate what is going on.

That is another benefit of this conference, so, for the new retailer Defendants who are on the conference, hopefully they, too, will come to better appreciate the processes we have in place in this litigation, how we are working, what our vision is, and the benefit of entering into the types of informal agreements such as generics and having the Court adopt an order so that there can be a give and take,

an informality, the ability to do things on an individualized basis, so if one retailer is slightly different from another, there is this meet and confer, and this understanding by the Plaintiffs to work with the Defendant as opposed to formal discovery that just comes, it comes in kind of one shape, one form, one size fits all, and makes it a little bit harder to be as nuanced as the informality of this process.

So, I hope that the retailer Defendants are comfortable with this process and will certainly feel free to ask any questions and that I certainly look forward to getting an agreement — rather, a proposed order that reflects the agreement in the way that at least those retailers who opted in will proceed with their discovery.

And I guess I just want to reiterate that, as with the other Defendants, I think we can all acknowledge that there are Defendants who feel, and maybe rightfully so, that they shouldn't be in the case at this time because they weren't involved in the allegations that have come forth in the complaint.

I think the Plaintiffs have articulated they recognize that, they didn't have all of the information, they are seeking to get that information, whether it is through the discovery agreements, census, Census Plus. I would just say to the retailer Defendants, as I said to everyone else, be patient. If you abide by the process I promise it will work the way it

is intended, and sooner rather than later that winnowing will occur, and if a party doesn't belong in this case, the party will get out.

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You have Mr. Pulaski's word, and he is part of the colead team, that that is the representation by the Plaintiffs, and so, again, give and take, and I think the result will be achieved. So, I wanted to make sure to reiterate that point as well.

If there is nothing further from the retailer end of discovery -- is that correct? I will just conclude with the catchall other issues, point five of the agenda.

MR. PULASKI: I think we are done, your Honor.

MS. JOHNSTON: Yes, your Honor. And apologies for my technical malfunction, but I think I caught most of what was said and I think that is accurate, and certainly the guidance is appreciated as we move towards closing this out.

THE COURT: If you didn't catch it all, I'm sure Mr. Pulaski and Ms. Finken will be happy to give you their version of what happened. There is always the transcript, too, to keep them honest.

The last issue, then, had to do with any new Defendant groups, distributors, repackagers. Mr. Petrosinelli, were you going to come on to frame this last issue with respect to the newest groups?

MR. PETROSINELLI: Yes, your Honor. Again, Joe

Petrosinelli of Williams and Connolly for Pfizer and one of the Defense coleads.

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Very quickly, this could be -- just to simply alert the Court, as your Honor knows, but with the addition of two newer groups, distributors and repackagers, and I think some of them are still appearing, I think it is not only fair, but it will help efficiency for they, too, to have a liaison much like the generics and the retailers do.

So, my suggestion to the Court on that, just in my coordinating counsel role, would be that once those two groups have all of their members appear, that they contact Special Master Dodge, who I'm sure would be in contact with me, but principally they contact Special Master Dodge and go through the same process that we went through with the generic Defendants and the retailers, and that is, hopefully by agreement they could put forward someone to be a liaison counsel, or if there is not agreement, your Honor could go through the same process as was done with the Plaintiffs in terms of a leadership application.

I think that is really all we need to do today, and if the Court agrees with that, just to let the parties know that is what the Court has in mind.

THE COURT: I do agree with that process. So, I would just ask that that process be followed, and for any repackager, distributor, you know, new parties, through counsel or any

other representatives on their behalf on the Zoom call today, to follow that process. It worked well. Having liaison counsel has just been integral, as you have probably seen and heard throughout this conference, and the ones we have have been doing an excellent job. We have Mr. Petrosinelli, who coordinates with everybody from the Defense, and it just makes for a nice teamwork approach, but be assured that your issues, which may be very individual to you, are always being heard and brought to the table through these channels.

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So, I will wait to hear more, but if there is agreement, I can enter an order similar to how I have done with the generics and with the retailer. If there is not agreement, that is fine, too. We had two days of interviews for Plaintiffs leadership, and the Court is certainly willing to entertain any kind of process that would bring forth the best and most appropriate person or persons to serve as liaison counsel on behalf of the distributors and repackagers.

Is that all on that issue, Mr. Petrosinelli?

MR. PETROSINELLI: Yes, your Honor, thank you.

THE COURT: Thank you. I think that brings us to the end. I know it is the end when I am the only one on the screen again, and I don't like to be the only one on the screen, so it is time for me to sign off.

Again, for the 150 of who have hung in here for the four hours, and a thank you to Ms. Stipes for going the whole

way without a break, thank you all. Much work was done to get the litigation to where it is. Much work was done to present all that you have done to the Court in a cogent and helpful way.

I just want to reiterate my gratitude for the hard work, the diligence, the collaboration, the cooperation, the desire to work together where the stakes are high for all parties. I recognize that. I don't want anyone to walk away from this conference feeling that it or he or she, an entity, a person has not been heard.

Counsel who have presented here today, in the Court's view, have done the very best effort to represent all of the interests. If today a particular issue of concern was not heard by the Court, be assured that there will always be a way and a time for you to be heard. So, please be patient, trust the process. I think much work remains to be done. I think this clarified some of those issues today, and I am grateful for that.

So, with that, I am going to conclude the conference, and wish everybody a nice rest of the day, upcoming weekend, and always to remain healthy, safe, and well during these times. Thank you.

(Thereupon, the hearing was concluded.)

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1	I certify that the foregoing is a correct transcript
2	from the record of proceedings in the above matter.
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4	Date: July 14, 2020
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6	Signature of Court Reporter
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